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REPLIMUNE GROUP, INC. Financial Statements For the Years Ended March 31, 2020, 2019 and 2018

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended March 31, 2020

OR

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission file number 001-38596

REPLIMUNE GROUP, INC.
(Exact name of registrant as specified in its charter)

Delaware	**82-2082553**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

500 Unicorn Park
Woburn MA 01801
(Address of principal executive offices)
(Zip Code)

(781) 222-9600
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	REPL	The Nasdaq Stock Market LLC (Nasdaq Global Select Market)

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No o

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.045 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer o	Accelerated filer o	Non-accelerated filer ☒	Smaller reporting company ☒ Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes o No ☒

The aggregate market value of the Common Stock held by non-affiliates of the registrant was approximately $178.0 million, based on the closing price of the registrant's Common Stock on September 30, 2019, the last business day of the registrant's most recently completed second fiscal quarter.

There were 36,784,130 shares of Common Stock outstanding as of May 29, 2020.

DOCUMENTS INCORPORATED BY REFERENCE

The registrant intends to file a definitive proxy statement pursuant to Regulation 14A within 120 days of the end of the fiscal year ended March 31, 2020. Portions of such definitive proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K.

REPLIMUNE GROUP, INC.
ANNUAL REPORT ON FORM 10-K
For the Year Ended March 31, 2020

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Special note regarding forward-looking statements

This Annual Report on Form 10-K contains forward-looking statements concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business operations and financial performance and condition. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify these forward-looking statements by the use of words such as "outlook," "believes," "expects," "potential," "continues," "may," "will," "should," "seeks," "approximately," "predicts," "intends," "plans," "estimates," "anticipates" or the negative version of these words or other comparable words. Such forward-looking statements are subject to various risks and uncertainties. Accordingly, there are or will be important factors that could cause actual outcomes or results to differ materially from those indicated in these statements. We believe these factors include, among other things:

- the timing, progress, and results of preclinical studies and clinical trials for our product candidates, including the timing of initiation and completion of studies or trials and related preparatory work and the period during which the results of the trials will become available;
- our ability to obtain additional funding as necessary;
- the timing, scope or likelihood of regulatory filings and approvals, including timing of our Biologics License Application, or BLA, and filing for, and final approval by the U.S. Food and Drug Administration, or the FDA, of, RP1 or any of our other product candidates;
- the timing, scope, or likelihood of foreign regulatory filings and approvals;
- our ability to develop our product candidates for use in combination with other checkpoint blockade therapies, including anti-PD-1;
- our ability to develop and advance any future product candidates into, and successfully complete, clinical trials;
- our expectations regarding the size of the patient populations for RP1 and our other product candidates if approved for commercial use;
- the costs of operating our in-house manufacturing facility;
- our estimates regarding expenses and capital requirements;
- the implementation of our business model and our strategic plans for our business, RP1 and our other product candidates;
- the rate and degree of market acceptance and clinical utility of RP1 and our other product candidates;
- the potential benefits of and our ability to establish or maintain future collaborations or strategic relationships;
- our ability to retain the continued service of our key professionals and to identify, hire and retain additional qualified professionals;
- our intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights covering RP1 and our other product candidates, claims others may make regarding rights in our intellectual property, and any potential infringement, misappropriation or other violation of any third-party intellectual property rights;
- our competitive position, and developments and projections relating to our competitors and our industry;
- negative developments in the field of immuno-oncology;

- the impact of laws and regulations;
- the impact of the COVID-19 coronavirus, or COVID-19, as a global pandemic and related public health issues;
- our ability to remediate the material weaknesses in internal control over financial reporting and to maintain effective internal control over financial reporting;
- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act of 2012; and
- the other risks and uncertainties described under "Risk factors."

The forward-looking statements made in this Annual Report on Form 10-K relate only to events as of the date on which the statements are made. These factors should not be construed as exhaustive and should be read in conjunction with the other cautionary statements that are included in this Annual Report on Form 10-K. Moreover, we operate in a competitive and rapidly changing environment. New risks and uncertainties emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this Annual Report on Form 10-K. We undertake no obligation to publicly update or review any forward-looking statement, whether as a result of new information, future developments or otherwise, except to the extent required by applicable law. You should not rely on forward-looking statements as predictions of future events. We may not actually achieve the plans, intentions, or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements.

PART I

Item 1. Business

Overview

We are a clinical-stage biotechnology company committed to applying our leading expertise in the field of oncolytic immunotherapy to transform the lives of cancer patients. We use our proprietary Immulytic platform to design and develop product candidates that are intended to maximally activate the immune system against cancer.

Oncolytic immunotherapy, which we intend to establish as the second cornerstone of immune-based cancer treatment, is an emerging class of immuno-oncology therapy, alongside checkpoint blockade, that exploits the ability of certain viruses to selectively replicate in and directly kill tumors, as well as induce a potent, patient-specific, anti-tumor immune response. Such oncolytic, or "cancer killing," viruses have the potential to generate an immune response targeted to an individual patient's particular set of tumor antigens, including neo-antigens that are uniquely present in tumors. Our product candidates incorporate multiple mechanisms of action into a practical "off-the-shelf" approach that is intended to maximize the immune response against a patient's cancer and to offer significant advantages over personalized vaccine approaches. We believe that the bundling of multiple approaches for the treatment of cancer into single therapies will simplify the development path of our product candidates, while also improving patient outcomes at a lower cost to the healthcare system than the use of multiple different drugs.

The foundation of our Immulytic platform consists of a proprietary, engineered strain of herpes simplex virus 1, or HSV-1, that has been "armed" with a fusogenic glycoprotein intended to substantially increase anti-tumor activity. Our Immulytic platform enables us to incorporate various genes into HSV-1 that are intended to further augment the inherent properties of HSV-1 in order to both directly destroy tumor cells and induce an anti-tumor immune response. We currently have three product candidates in our development pipeline, RP1, our lead product candidate, and additionally RP2 and RP3.

We are currently conducting a number of clinical trials of RP1, both as a monotherapy and in combination with anti-PD-1 therapy, with a focus on immune-responsive tumors. We are conducting a randomized, controlled Phase 2 clinical trial of RP1 in approximately 240 patients with cutaneous squamous cell carcinoma, or CSCC, RP1's lead indication. This registration directed clinical trial is evaluating RP1 in combination with cemiplimab, an anti-PD-1 therapy developed by Regeneron Pharmaceuticals, Inc., or Regeneron, versus cemiplimab alone. Regeneron has granted to us a non-exclusive royalty-free license to cemiplimab for use in this trial, funding one-half of the clinical trial costs and supplying cemiplimab at no cost to us. We have also opened for enrollment a Phase 1b clinical trial of single agent RP1 in solid organ transplant recipients with CSCC, which we believe to be potentially registrational (in its own right or, subject to discussion with regulatory authorities, following enrollment of additional patients). We have entered into a collaboration with Bristol-Myers Squibb Company, or BMS, under which it has granted us a non-exclusive, royalty-free license to, and is supplying at no cost, its anti-PD-1 therapy, nivolumab, for use in combination with RP1 in a multi-cohort clinical trial. We are currently enrolling a 125-patient extension cohort of RP1 combined with nivolumab in anti-PD-1 refractory cutaneous melanoma. We initiated this cohort after completing enrollment in a prior Phase 2 cohort in the same clinical trial of approximately 30 patients with melanoma. The data generated in the melanoma cohort demonstrated that RP1 combined with nivolumab has the potential to treat anti-PD-1 refractory melanoma. We also believe this cohort to be potentially registrational (in its own right or, subject to discussion with regulatory authorities, following enrollment of additional patients). We continue to enroll patients in other Phase 2 cohorts of approximately 30 patients each, testing RP1 in combination with nivolumab in non-melanoma skin cancers and microsatellite instability high, or MSI-H/dMMR, tumors under our collaboration with

BMS. Due in part to COVID-19 related disruptions, we expect that the non-melanoma skin cancer cohort to be fully accrued by the end of 2020. Similarly, it is likely that accumulating sufficient data to inform a decision as to whether to pursue MSI-H/dMMR tumors into registration-directed development will be delayed into 2021.

In addition, as a result of the recently altered competitive landscape, we recently announced our intention to replace a 30-patient bladder cancer cohort with a cohort of patients with anti-PD-1 refractory non-small cell lung cancer, or NSCLC. We intend to file a protocol amendment with the applicable regulatory authorities in the near term in order to reflect this change.

We are also developing additional product candidates, RP2 and RP3, that have been further engineered to enhance anti-tumor immune responses and are intended to address additional tumor types. In addition to the expression of GALV-GP R(-) and human GM-CSF, RP2 has been engineered to express an antibody-like molecule intended to block the activity of CTLA-4, a protein that inhibits the immune response to tumors. RP3 has also been engineered with the intent to further stimulate an anti-tumor response through activation of the immune co-stimulatory pathways through expression of the ligands for CD40 and 4-1BB.

We initiated the Phase 1 clinical trial of RP2 in October 2019. The Phase 1 clinical trial of RP2 is being conducted as a collaboration with BMS, under which BMS has granted us a non-exclusive, royalty-free license to, and will supply at no cost, nivolumab, for use in combination with RP2. We expect to release initial data from this Phase 1 clinical trial in the second half of 2020. We intend to file an investigational new drug application, or IND, and/or foreign equivalents for RP3 and, assuming regulatory clearance, enter clinical development during 2020. IND and/or foreign equivalent enabling studies of RP3 are currently underway.

RP1, RP2 and RP3 are administered by direct injection into solid tumors, guided either visually or by ultrasound or other imaging methods. We believe that direct injection maximizes virus-mediated tumor cell death, provides the most efficient delivery of virus-encoded immune activating proteins into the tumor with the goal of activating systemic immunity, and limits the systemic toxicities that could be associated with intravenous administration. Activation of systemic immunity through local administration is intended to lead to the induction of anti-tumor immune responses leading to clinical response of tumors that have not themselves been injected, which is known as an "abscopal" effect.

Our approach—Oncolytic immunotherapy

Our product candidates are designed to induce a robust immune response against a patient's cancer and turn immunologically "cold" tumors "hot." To achieve this objective, we use oncolytic immunotherapies that combine multiple mechanisms of action in a single product candidate. We believe our product candidates will initiate or enhance an immune response in patients with no or minimal pre-existing cancer immunity, including to tumor neo-antigens, and thereby increase the effectiveness of immune checkpoint blockade therapies.

Our product candidates are intended to act at several key points in the pathways involved in the initiation of an immune response. Following direct injection into tumors, our viruses replicate in cancer cells and then lyse, or break them open, releasing tumor antigens, including neo-antigens specific to the patient, which could otherwise be hidden from the immune system. This process of necrotic cell death releases intra-cellular markers of "danger," the danger associated molecular patterns, or DAMPs, while the virus produces pathogen associated markers of danger, or PAMPs. These trigger various pathways of the innate immune system, including the STING pathway and pathways mediated through toll-like receptors, or TLRs, each resulting in the production of interferon. Innate immune activation would be expected to itself provide anti-tumor effects, as interferon activates natural killer cells which can destroy tumor cells. Innate immune activation would also be expected to help trigger adaptive anti-cancer immunity, in which antigen presenting cells, or APCs, are attracted to the injected tumor.

APCs internalize cancer antigens, including neo-antigens, and traffic back to the draining lymph nodes where they present the antigens to T cells. Primed with the antigens, these T cells then proliferate and disperse systemically to seek and destroy cancer cells with the same antigen profile throughout the body, resulting in the potential destruction of distant tumor deposits.

To further augment these intended effects, our product candidates are intended to genetically encode and express multiple potent, cell-killing and immune-stimulating proteins in the tumor—in other words, our product candidates are "armed" with these therapeutic genes.

We believe that our ability to incorporate multiple mechanisms of action into a practical "off-the-shelf" approach to initiating or enhancing an anti-tumor immune response, including to neo-antigens, will offer significant advantages over the various approaches to immune activation that are currently in development, including personalized vaccine treatments. Tumor neo-antigens are uniquely present in tumors, rather than normal tissue, because they result from the genetic changes that occur as cancer develops. Unlike the antigens present in normal tissue, the immune system identifies neo-antigens as foreign. As a result, the immune system is able to mount an immune response to tumor neo-antigens in the same way that it would to the antigens contained in disease-causing micro-organisms, which the immune system also identifies as foreign. Researchers believe immune responses to tumor neo-antigens are particularly important in the immune system's ability to combat cancer, and as a consequence various "personalized vaccine" approaches to generating immune responses to tumor neo-antigens are in development. These approaches are generally both expensive and time consuming because a vaccine cannot be designed and manufactured until a tumor biopsy is taken and analyzed in the laboratory to identify the mutated tumor antigens that will be targeted by the treatment. We also believe that our "off-the-shelf" approach may offer significant advantages over other approaches to anti-cancer immune activation that only target a single pathway of the immune system, as is the case with most of the other immuno-oncology therapies currently under development. Importantly, our product candidates are intended to maximally activate an immune response against cancer, which we believe is the missing element needed to allow anti-PD-1 or anti-PD-L1 therapy to treat more patients and tumor types, unlike some other therapies that are intended to act by blocking additional defense mechanisms against an anti-tumor immune response once it has been initiated.

Our Immulytic platform and product candidates

The foundation of our oncolytic immunotherapy product candidates, which we call our Immulytic platform, consists of a proprietary strain of HSV-1 that we have engineered to replicate selectively in tumors and to express a fusogenic glycoprotein, a protein that triggers the fusion of the membranes between cells. HSV-1 is both highly cell lytic and inflammatory, and also has a large carrying capacity, which makes it possible to incorporate multiple genes encoding therapeutic proteins. We believe our combination of HSV-1 with the expression of the fusogenic glycoprotein increases the natural ability of HSV-1 to kill tumor cells and to induce an anti-tumor immune response. The fusogenic functionality of our product candidates is intended not only to increase the number of tumor cells that are killed, but also to cause highly immunogenic death of tumor cells. We believe that these factors will increase the potency of the systemic anti-tumor immune response that is generated by our product candidates. With the intention of further amplifying the anti-tumor response further, we have also engineered product candidates that express a range of additional potent, immune activating genes encoding therapeutic proteins in tumors.

Our lead product candidate, RP1, serves as the base from which our additional product candidates, RP2 and RP3, are being developed to express additional therapeutic proteins. We believe that our sequential development approach of further enhancing our product candidates with additional therapeutic proteins reduces clinical risk, as we are able to study the safety profile of each therapeutic protein prior to moving to the next product candidate with an additional therapeutic protein that is intended to provide more potent anti-tumor immune effects.

Lead product candidate: RP1

Our lead product candidate, RP1, is a selectively replicating version of HSV-1 that expresses GALV-GP R(-) and human GM-CSF. RP1 has the following properties:

- we have deleted the ICP34.5-encoding gene, which enables tumor-selective virus replication;
- we have deleted the ICP47-encoding gene, which is intended to prevent the inhibition of the antigen presentation pathway otherwise caused by ICP47 binding to the transporter associated with antigen presentation. ICP47 deletion is also intended to result in the increased and earlier expression of the HSV-1 US11 gene by placing the HSV-1 US11 gene under the control of ICP47 promoter which we believe will increase virus replication in tumors without reducing tumor-selectivity; and
- we have inserted the sequences for GALV-GP R(-) and human GM-CSF, resulting in the expression of these therapeutic proteins with the intention of increasing both the direct tumor cell killing and the potency of the anti-tumor immune response that is induced.

We have developed RP1 as a monotherapy and for use in combination with immune checkpoint blockade therapy, particularly therapies targeting PD-1 or PD-L1. We believe that the robust release of tumor antigens and the highly immunogenic tumor cell death intended to be caused by RP1 will further increase the previously observed synergy between oncolytic viruses and immune checkpoint blockade therapy.

Clinical Trials in RP1

We are currently conducting a randomized, controlled Phase 2 clinical trial testing RP1 in combination with cemiplimab versus cemiplimab alone in approximately 240 patients in CSCC. This clinical trial is being conducted under a collaboration agreement with Regeneron, pursuant to which Regeneron has granted us a non-exclusive, royalty-free license to cemiplimab for use in the clinical trial and is funding one-half of the clinical trial costs and supplying cemiplimab at no cost to us. Enrollment at some of our clinical trial sites in the United States and Australia have been placed on hold as a result of the COVID-19 pandemic, which may impact the anticipated timing of the clinical trial. In addition to our clinical trial sites in Australia and the United States, we intend to open clinical trial sites in Canada, the United Kingdom, France and Germany, and potentially other countries. If compelling clinical data are generated demonstrating the benefits of the combined treatment in this clinical trial, we believe the data from this Phase 2 clinical trial could support a filing with regulatory authorities for marketing approval. Recruitment into this Phase 2 clinical trial is expected to take approximately eighteen to twenty-four months and we expect the primary data readout from the clinical trial in 2022.

We have also opened for enrollment a Phase 1b clinical trial of single agent RP1 in solid organ transplant recipients in approximately 30 patients with CSCC, which we believe to be potentially registrational (in its own right or, subject to discussion with regulatory authorities, following enrollment of additional patients).

We are further conducting a Phase 1/2 clinical trial of RP1 in collaboration with BMS. Pursuant to our collaboration, BMS has granted us a non-exclusive, royalty-free license to, and is supplying at no cost, nivolumab, for use in combination with RP1 in this clinical trial. We have completed enrollment of the Phase 1 part of the clinical trial, in which we enrolled 36 patients with advanced heavily pre-treated cancers who were refractory to available therapy. RP1 alone was administered up to five times at various dose levels injected into a single tumor to determine the recommended Phase 2 dose (N=22), following which RP1 was administered up to eight times at the recommended dose in combination with nivolumab starting with the second dose of RP1 (N=14). Based on the data, which we believe showed a favorable safety profile for both RP1 alone and in combination with nivolumab,

the RP1 dosing regimen moved forward into Phase 2 development with an initial dose of up to 10mL of $1x10^6$ pfu/ml followed by subsequent doses of up to 10mL of $1x10^7$ pfu/ml.

In the dose rising monotherapy part of the Phase 1/2 clinical trial, RP1 was associated with tumor destruction, including delayed systemic post-study tumor reduction without further therapy. In the combination portion of the Phase 1 part of the clinical trial, anti-tumor activity was demonstrated in multiple patients with a variety of tumor types, particularly in CSCC and melanoma, but also in microsatellite instability high (MSI-H) colorectal cancer and esophageal cancer patients. Of particular note, substantial tumor reduction was observed in a number of patients after just the first dose of RP1, but before the introduction of nivolumab two weeks later and responses of uninjected tumors were also observed. Biomarker data further confirmed the mechanism of action of RP1 alone and in combination with nivolumab, suggesting that RP1 provides broad anti-tumor immune activation. Increases in CD8 T Cells and PD-L1 were seen in serial tumor biopsies across tumor types, and we believe that the kinetics of virus detection suggests that robust virus replication in tumors occurs.

The Phase 2 part of this clinical trial was originally designed to assess the safety and efficacy of RP1 in combination with nivolumab in four 30-patient cohorts of patients with melanoma, non-melanoma skin cancers, bladder cancer and MSI-H/dMMR tumors.

We have completed enrollment in the Phase 2 part of this clinical trial in the cohort of approximately 30 patients with melanoma. As a result of what we believe to be encouraging clinical data in this patient group with RP1 combined with nivolumab, we have initiated recruitment in a further cohort of 125 patients with anti-PD-1 refractory melanoma, which we believe to be potentially registrational (in its own right or, subject to discussion with regulatory authorities, following enrollment of additional patients). In 16 patients dosed in this setting, as of May 2020, five have responded to treatment and two further patients remain on treatment with the opportunity of response. These patients would not generally have been expected to respond to a second line of anti-PD-1 therapy alone. We are continuing to enroll cohorts of approximately 30 patients with non-melanoma skin cancers and MSI-H/dMMR tumors, although enrollment has slowed due in part to the COVID-19 pandemic. Of note, within the non-melanoma skin cancer cohort, as of May 2020, six of the seven patients enrolled and with available follow up data in our lead indication of CSCC had responded, with four complete responses. We believe this data, while in a small number of patients, differentiates the combination data of RP1 and anti-PD-1 therapy versus anti-PD-1 therapy alone for which complete responses are infrequent. In addition, as a result of the recently altered competitive landscape, we recently announced our intention to replace a 30-patient bladder cancer cohort under the BMS collaboration with a cohort of patients with anti-PD-1 refractory NSCLC. We intend to file a protocol amendment with the applicable regulatory authorities in the near term in order to reflect this change.

Pipeline product candidate: RP2

We have designed our RP2 product candidate to express an anti-CTLA-4 antibody-like protein intended to block the inhibition of the immune response otherwise caused by CTLA-4. We believe that RP2 may offer advantages compared with current CTLA-4 approaches, including ipilimumab. By expressing anti-CTLA-4 only locally in the tumor and draining lymph nodes, we believe that activity will be retained, but that toxicity will be reduced. We intend that our RP2 product candidate will be used in combination with anti-PD-1 therapy, which we believe will result in both synergy with the oncolytic virus and the expression of the anti-CTLA-4 in the tumor.

We initiated the Phase 1 clinical trial with RP2 in October 2019. The Phase 1 clinical trial of RP2 is also being conducted as a collaboration with BMS, under which BMS has granted us a non-exclusive, royalty-free license to, and will supply at no cost, nivolumab, for use in combination with RP2. We expect to release initial data from this Phase 1 clinical trial in the second half of 2020. Based on the

data generated to date, we have decided to amend the protocol to allow for an expansion of the second part of this clinical trial (of RP2 combined with nivolumab) from 12 to 30 patients.

Pipeline product candidate: RP3

We have designed our RP3 product candidate to express immune-activating proteins that stimulate T cells, in addition to anti-CTLA-4 and GALV-GP R(-). These immune activating proteins are the ligands for two immune co-stimulatory pathways responsible for T cell proliferation and/or activation, the CD40 and 4-1BB pathways. We intend to file an IND and/or foreign equivalents for RP3 and, assuming regulatory clearance, enter clinical development during 2020. IND and/or foreign equivalent enabling studies of RP3 are currently underway.

The COVID-19 pandemic

In December 2019, a novel strain of coronavirus, which causes the disease known as COVID-19, was reported to have surfaced in Wuhan, China. In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic, which continues to spread throughout the United States and globally. We could be materially and adversely affected by the risks, or the public perception of the risks, related to an epidemic, pandemic, outbreak, or other public health crisis, such as the COVID-19 pandemic. We are monitoring the global crisis caused by the COVID-19 pandemic and have taken steps to identify and mitigate the adverse impacts on, and risks to, our business posed by its spread and actions taken by governmental and health authorities to address the COVID-19 pandemic. The spread of COVID-19 has caused us to modify our business practices, including implementing a global work from home policy for certain employees who are able to perform their duties remotely and restricting all nonessential travel, and we expect to continue to take actions as may be required or recommended by government authorities or as we determine are in the best interests of our employees, the patients we serve and other business partners in light of COVID-19. The COVID-19 pandemic has delayed, and we expect it to continue to delay, the timing of patient enrollment and treatment in certain of our ongoing clinical trials. However, the extent and duration of such delays, is currently unknown and has and will likely continue to vary by clinical trial site. In addition, we may incur unforeseen costs as a result of disruptions in clinical supply or preclinical study or clinical trial delays. The impact of COVID-19 on our business results will largely depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions, the ultimate impact on financial markets and the global economy, and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. See "Risk factors—Our financial condition and results of operations could be adversely affected by the recent novel coronavirus disease-2019, or COVID-19, outbreak." in Part I, Item 1A of this Annual Report on Form 10-K.

Intellectual property

We believe our rights under issued patents, if obtained, and patent applications will provide a competitive advantage. Our success depends in part on our ability to obtain and maintain proprietary protection for our product candidates, technology and know-how, to operate without infringing the proprietary rights of others and to prevent others from infringing upon our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing United States and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary position.

For the core technology in our Immulytic platform and each of our product candidates, we have filed six patent applications under the Patent Cooperation Treaty, or PCT. Five of these PCT

applications have entered the national phase and are pending in a range of countries, and one is still in the international phase. Three US patents have been granted. Other than the foregoing, none of our PCT-derived patent applications or U.S. provisional applications have been granted by a patent office. Examination has started only in connection with the European and US national phase applications. A notice of allowance has been issued on one European application.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, the patent term of a patent that covers an FDA-approved drug may also be eligible for patent term extension, which permits patent term restoration of a portion of the patent term lost during the U.S. clinical development and FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under clinical development in the United States and the length of time the drug is under regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our products receive FDA approval, and if and when patents grant, we expect to apply for patent term extensions on patents covering those products. We plan to seek patent term extensions to any of our issued patents in any jurisdiction where these are available, however there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions.

We may rely, in some circumstances, on trade secrets to protect our technology. We seek to protect our proprietary technology and processes, in part, by confidentiality agreements with our employees, consultants, scientific advisors and other contractors, as well as physical security of our premises and our information technology systems.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary rights. We compete in the highly competitive markets that address cancer and face significant competition from many sources, including pharmaceutical, biopharmaceutical and biotechnology companies, as well as universities and private and public research institutions. Many of our competitors have significantly greater financial, manufacturing, marketing and drug development resources than we do. Large biopharmaceutical companies in particular have extensive experience in clinical testing and in obtaining regulatory approvals for drugs and biologicals. These companies also have significantly greater research capabilities than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies or universities and research institutions.

Our competitors fall primarily into the following groups of treatment:

- traditional cancer therapies, including chemotherapy, surgery, radiation and targeted therapies;
- approved immunotherapy antibodies and immunotherapy antibodies in clinical trials;
- oncolytic immunotherapies, including T-Vec and other oncolytic immunotherapies in clinical trials;
- therapies aimed at activating innate immunity such as those targeting STING and TLRs;
- cancer vaccines including personalized vaccines and those targeting tumor neo-antigens; and

- cell-based therapies, such as CAR-T, T cell receptor-based, and NK cell therapies.

Our commercial opportunity will be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects, are easier to administer or are less expensive alone or in combination with other therapies than any products that we may develop alone or in combination with other therapies, especially if these get to market sooner than our products. These third parties also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business.

Our oncolytic product candidates, if and when marketed, will compete with a number of drugs that are currently marketed or in development that also target cancer but that utilize a different mechanism of action. To compete effectively with these agents, our product candidates will need to demonstrate advantages that lead to improved clinical efficacy and safety compared with these competitors. At the same time, however, we believe that our oncolytic product candidates, if and when ultimately marketed, would likely be used principally in combination with checkpoint blockade therapies in addition to existing cancer therapies, including surgery, chemotherapy, radiation therapy and other biological therapies such as antibodies targeting particular surface receptors. We therefore believe that our product candidates, if and when marketed, would largely complement rather than compete directly with these existing treatment options.

We do, however, expect to face direct and increasing competition from a number of companies that are also seeking to develop cancer therapies based on oncolytic viruses and other ways to prime the immune system, including neo-antigen vaccination. We believe that our ability to successfully compete will depend, among other things, on our ability to:

- expeditiously advance the development of our product candidates;
- design, enroll patients in and successfully complete appropriate clinical trials in a timely fashion;
- gain regulatory approval for our product candidates in their first indications as well as further indications;
- establish collaborations and partnerships for the development and marketing of our product candidates;
- commercialize our product candidates successfully, including convincing physicians, insurers and third-party payors of the safety and efficacy of our product candidates over currently approved therapies;
- secure and protect intellectual property rights based on our innovations; and
- manufacture or otherwise obtain and sell commercial quantities of future products to the market.

Manufacturing and suppliers

We have established an operations leadership team with extensive experience in manufacturing biologics based on viruses, including oncolytic products and gene therapy products, and in the construction, validation, approval and operation of facilities designed to manufacture biologics. Our team has already developed a robust and reproducible manufacturing process for our product candidates. We are also developing our product candidates for maximum practicality of use compared with some other oncolytic immunotherapies; in particular, our product candidates do not require refrigeration at -70^0 Celsius at clinical sites.

To date, our third-party contract manufacturer in Europe has been responsible for sourcing raw materials for use in the manufacture, in accordance with cGMP, of our product candidates for use in our planned early clinical trials. We currently use fetal bovine sera, a commonly used growth supplement, in the initial growth of the mammalian cells used in the production of our viral product candidates and a recombinant human protein to increase the stability of our drug formulation. We are in the process of developing our raw material supply chain for our product candidates as part of the process of establishing our own manufacturing facility and intend to enter into commercial supply, collaboration or similar agreements prior to conducting advanced clinical trials.

We have completed the build-out of, and obtained an occupancy certificate with respect to, our approximately 63,000 square foot manufacturing facility in Framingham, Massachusetts, where we plan to operate our own in-house manufacturing facility in order to secure supplies for pivotal studies and commercial launch. The facility has been designed to allow us to produce enough material to cover full global commercialization of all our current product candidates. The facility is intended to give us control over key aspects of the supply chain for our products and product candidates.

By establishing our own manufacturing facility, we aim to minimize or eliminate our reliance on contract manufacturing organizations, which typically have limited capacity at commercial scale and quality. We believe that having control over the whole manufacturing process will allow us to reduce cycle times and cost of goods for commercial production and to shorten overall timelines for new product candidates in our development pipeline, as well as help us to develop drug formulations or presentations to simplify distribution and/or administration of future oncolytic immunotherapies. We also believe that having a dedicated manufacturing facility will allow us to optimize commercial-scale processes and to develop a suitable workforce capable of supporting market launch.

Sales and marketing

None of our product candidates has been approved for sale. If and when our product candidates receive marketing approval, we intend to commercialize them on our own in the United States and potentially with pharmaceutical or biotechnology partners in other geographies. We currently have no sales, marketing or commercialization capabilities and have no experience as a company doing such activities. However, we intend to build the necessary capabilities and infrastructure over time following the advancement of our product candidates. Clinical data, the size of the opportunity and the size of the commercial infrastructure required will influence our commercialization plans and decision making.

Collaborations

BMS

On February 26, 2018, we entered into a Clinical Trial Collaboration and Supply Agreement with BMS. Pursuant to the agreement, BMS will provide to us, at no cost, nivolumab, its anti-PD-1 therapy, for use in combination with RP1 in our ongoing Phase 1/2 clinical trial. Under the agreement, we will sponsor, fund and conduct the clinical trial in accordance with an agreed-upon protocol. Under the agreement, BMS has granted us a non-exclusive, non-transferrable, royalty-free license (with a right to sublicense) under its intellectual property to use nivolumab in the clinical trial and has agreed to supply nivolumab, at no cost, for use in the clinical trial. Both parties will own the study data produced in the clinical trial, other than study data related solely to nivolumab, which will belong solely to BMS, or study data related solely to RP1, which will belong solely to us.

In January 2020, the Company and BMS expanded the scope of the Clinical Trial Collaboration and Supply Agreement to provide that BMS will supply to the Company, at no cost, nivolumab for use in combination with RP1 in an additional cohort of 125 patients with anti-PD-1 refractory melanoma. In May 2020, the Company and BMS agreed to replace the 30-patient bladder cancer cohort in the clinical trial with a cohort of patients with anti-PD-1 refractory NSCLC. Additionally, the Phase 1

clinical trial of RP2 is also being conducted in collaboration with BMS, under which BMS has granted us a non-exclusive, royalty-free license to, and will supply at no cost, nivolumab, for use in combination with RP2.

Unless earlier terminated, the agreement will remain in effect until the completion of the clinical trial, all related clinical trial data have been delivered to both parties and the completion of any statistical analyses and bioanalyses contemplated by the clinical trial protocol or any analysis otherwise agreed upon by the parties. The agreement may be terminated by either party in the event of an uncured material breach by the other party, in the event the other party is insolvent or in bankruptcy proceedings or for safety reasons. Upon termination, the licenses granted to us to use nivolumab in the clinical trial will terminate. The agreement contains representations, warranties, undertakings and indemnities customary for a transaction of this nature.

Regeneron

On May 29, 2018, we entered into a Master Clinical Trial Collaboration and Supply Agreement with Regeneron. Pursuant to the agreement, we agreed to undertake one or more clinical trials with Regeneron for the administration of our product candidates in combination with cemiplimab, an anti-PD-1 therapy developed by Regeneron, across multiple solid tumor types, the first of which is intended to be our planned Phase 2 clinical trial of RP1 in patients with CSCC. Each clinical trial will be conducted pursuant to an agreed study plan which, among other things, will identify the name of the sponsor and which party will manage the particular study, and include the protocol, the budget and a schedule of clinical obligations. The first study plan related to the Phase 2 clinical trial has been agreed.

Pursuant to the terms of the agreement, each party granted the other party a non-exclusive license of their respective intellectual property and agreed to contribute the necessary resources to fulfill their respective obligations, in each case, under the terms of the agreed study plans. Development costs of a particular clinical trial will be split equally. The agreement contains certain covenants that restrict us from entering into a third-party arrangement with respect to the use of our product candidates in combination with an anti-PD-1 therapy and that restrict Regeneron from entering into a third-party arrangement with respect to the use of cemiplimab in combination with an HSV-1 based product, in each case, for the treatment of a tumor type that is the subject of a clinical trial to which the covenants apply. Unless otherwise mutually agreed in a future study plan, these covenants are only applicable to our planned Phase 2 clinical trial in CSCC and expire upon the one-year anniversary of the commencement of the applicable study plan.

The agreement may be terminated by either party if there is no active study plan for which a final study report has not been completed, the parties have not entered into a study plan for an additional clinical trial within a period of time after the delivery of the most recent final study report or in the event of a material breach. The agreement contains representations, warranties, undertakings and indemnities customary for a transaction of this nature.

Regulatory matters

Government authorities in the United States, at the federal, state, and local level, and in other countries, extensively regulate, among other things, the research, development, testing, approval, manufacture, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, import, and export of biopharmaceutical products such as those we are developing. In addition, manufacturers of biopharmaceutical products participating in Medicaid and Medicare are required to comply with mandatory price reporting, discount, and rebate requirements. The processes for obtaining regulatory approvals in the United States and in foreign countries, along with compliance

with applicable statutes and regulations, require the expenditure of substantial time and financial resources.

FDA and EU regulation

In the United States, the FDA regulates biologics under the Federal Food, Drug, and Cosmetic Act, or FDCA, the Public Health Services Act, or PHSA, and their implementing regulations. The process required by the FDA before product candidates may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies, and formulation studies in compliance with GLP regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin at United States clinical trial sites;
- approval by an IRB for each clinical site, or centrally, before each trial may be initiated;
- adequate and well-controlled human clinical trials to establish the safety, purity, and potency of the proposed product candidate for its intended use, performed in accordance with GCPs;
- development of manufacturing processes to ensure the product candidate's identity, strength, quality, purity, and potency;
- submission to the FDA of a BLA;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the products are produced to assess compliance with current cGMPs, and to assure that the facilities, methods, and controls are adequate to preserve the therapeutics' identity, strength, quality, purity, and potency as well as satisfactory completion of an FDA inspection of selected clinical sites and selected clinical investigators to determine GCP compliance; and
- FDA review and approval of the BLA to permit commercial marketing for particular indications for use.

Preclinical studies and IND submission

The testing and approval process of product candidates requires substantial time, effort, and financial resources. Satisfaction of the FDA's pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease. Preclinical studies include laboratory evaluation of chemistry, pharmacology, toxicity, and product formulation, as well as animal studies to assess potential safety and efficacy. Such studies must generally be conducted in accordance with the FDA's GLPs. Prior to commencing the first clinical trial at a United States investigational site with a product candidate, an IND sponsor must submit the results of the preclinical tests and preclinical literature, together with manufacturing information, analytical data, any available clinical data or literature, and proposed clinical study protocols among other things, to the FDA as part of an IND.

An IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, notifies the applicant of safety concerns or questions related to one or more proposed clinical trials and places the trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during trials due to safety concerns or non-compliance. As a result, submission of an IND may not result in FDA authorization to commence a clinical trial. A

separate submission to an existing IND must also be made for each successive clinical trial conducted during product development.

Clinical trials

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with federal regulations and GCP requirements, which include the requirements that all research subjects provide their informed consent in writing for their participation in any clinical trial, as well as review and approval of the study by an IRB. Investigators must also provide certain information to the clinical trial sponsors to allow the sponsors to make certain financial disclosures to the FDA. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the trial procedures, the parameters to be used in monitoring safety, the effectiveness criteria to be evaluated, and a statistical analysis plan. A protocol for each clinical trial, and any subsequent protocol amendments, must be submitted to the FDA as part of the IND. In addition, an IRB at each study site participating in the clinical trial or a central IRB must review and approve the plan for any clinical trial, informed consent forms, and communications to study subjects before a study commences at that site. An IRB considers, among other things, whether the risks to individuals participating in the trials are minimized and are reasonable in relation to anticipated benefits, and whether the planned human subject protections are adequate. The IRB must continue to oversee the clinical trial while it is being conducted. Once an IND is in effect, each new clinical protocol and any amendments to the protocol must be added to the IND for FDA review, and to the IRB for approval. If a product candidate is being investigated for multiple intended indications, separate INDs may also be required. Progress reports detailing the results of the clinical trials must also be submitted at least annually to the FDA and the IRB and more frequently if serious adverse events or other significant safety information is found.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements or if the trial poses an unexpected serious harm to subjects. The FDA or an IRB may also impose conditions on the conduct of a clinical trial. Clinical trial sponsors may also choose to discontinue clinical trials as a result of risks to subjects, a lack of favorable results, or changing business priorities.

Information about certain clinical trials, including a description of the study and study results, must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on their clinicaltrials.gov website. Manufacturers or distributors of investigational products for the diagnosis, monitoring, or treatment of one or more serious diseases or conditions must also have a publicly available policy on evaluating and responding to requests for expanded access requests.

Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor that regularly reviews accumulated data and advises the study sponsor regarding the continuing safety of the trial. This group may also review interim data to assess the continuing validity and scientific merit of the clinical trial. This group receives special access to unblinded data during the clinical trial and may advise the sponsor to halt the clinical trial if it determined there is an unacceptable safety risk for subjects or on other grounds, such as no demonstration of efficacy.

Moreover, certain studies involving recombinant and synthetic nucleic acid molecules are subject to review by Institutional Biosafety Committees, or IBCs, under the National Institutes of Health Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.

The manufacture of investigational biologics for the conduct of human clinical trials is subject to current cGMP requirements. Investigational biologics and active ingredients imported into the United States are also subject to regulation by the FDA. Further, the export of investigational products outside of the United States is subject to regulatory requirements of the receiving country as well as United States export requirements under the FDCA.

In general, for purposes of BLA approval, human clinical trials are typically conducted in three sequential phases, which may overlap or be combined.

- Phase 1—Trials are initially conducted in healthy human volunteers or subjects with the target disease or condition and test the product candidate for safety, dosage tolerance, structure-activity relationships, mechanism of action, absorption, metabolism, distribution, and excretion. If possible, Phase 1 trials may also be used to gain an initial indication of product effectiveness.

- Phase 2—Controlled trials are conducted in limited subject populations with a specified disease or condition to evaluate the effectiveness of the product candidate for a particular indication or indications, identify optimal dosages, dosage tolerance and schedule, possible adverse effects and safety risks, and expanded evidence of safety.

- Phase 3—These adequate and well controlled clinical trials are undertaken in expanded subject populations, generally at geographically dispersed clinical trial sites, to generate enough data to provide statistically significant evidence of clinical efficacy and safety of the product for approval, to establish the overall risk benefit profile of the product, and to provide adequate information for the labeling of the product. Typically, two Phase 3 trials are required by the FDA for product approval. Under some limited circumstances, however, approval may be based upon a single adequate and well-controlled clinical trial plus confirmatory evidence or a single large multicenter trial without confirmatory evidence.

Additional kinds of data may also help to support a BLA, such as patient experience data and real-world evidence. Real world evidence may also be used to assist in clinical trial design. For appropriate indications sought through supplemental BLAs, data summaries may provide marketing application support. For genetically targeted products and variant protein targeted products intended to address an unmet medical need in one or more patient subgroups with a serious or life threatening rare disease or condition, the FDA may allow a sponsor to rely upon data and information previously developed by the sponsor or for which the sponsor has a right of reference, that was submitted previously to support an approved application for a product that incorporates or utilizes the same or similar genetically targeted technology or a product that is the same or utilizes the same variant protein targeted drug as the product that is the subject of the application.

Further, under certain circumstances, manufacturers and sponsors of investigational biopharmaceutical product candidates can provide access to the product candidates to certain qualifying patients outside of clinical trials. For instance, under the FDA's expanded access program, with FDA approval and subject to certain requirements, sponsors may provide access to product candidates to patients with serious or immediately life threatening diseases or conditions for which there is no comparable or satisfactory alternative therapy, provided that the potential patient benefit justifies the risks, the risks are not unreasonable in the context of the disease or condition to be treated, and the provision of the product candidate for the requested use will not interfere with clinical investigations. The specific expanded access criteria and requirements depend on the number of expanded access patients. Sponsors and investigators of expanded access programs must still comply with the FDA's clinical trial guidelines and are subject to protection regulations. Federal and state laws in the United States, referred to as right to try laws, also establish a separate mechanism through which certain patients with life threatening diseases or conditions, who have exhausted all approved treatment options and are unable to participate in a clinical trial, may request access to investigational product candidates that have completed a Phase 1 clinical trial. While certain criteria must be met for a patient to be

eligible for access to product candidates under right to try laws, these laws do not require the FDA to approve the use of the product candidate and do not require compliance with the majority of the FDA's clinical trial regulations.

The FDA may also require, or companies may conduct, additional clinical trials for the same indication after a product is approved. These so-called Phase 4 trials may be made a condition to be satisfied after approval. The results of Phase 4 trials can confirm or refute the effectiveness of a product candidate and can provide important safety information.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product candidate as well as finalize a process for manufacturing the product in commercial quantities in accordance with current cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, manufacturers must develop methods for testing the identity, strength, quality, potency, and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

In relation to the clinical trial in the United Kingdom and in so far as trials will be conducted in other countries with a view to obtaining a marketing authorization from the European Medicines Agency, there are broadly equivalent GLP, GCP, cGMP and ethical approval requirements and European Union regulatory rules that are implemented nationally. However, enforcement of such rules is conducted by the regulatory authority in which the trial is carried out, which is the MHRA in the United Kingdom.

Combination Products

Biologic products may be regulated as combination products if they are intended for use in conjunction with medical devices, such as a delivery devices. In such cases, the use of the two products together (i.e., the biological product and the device) must be shown to be safe and effective for the proposed intended use, and, the labeling of the two products must reflect their combined use. In some cases, the device component may require a separate premarket submission; for example, when the device component is intended for use with multiple therapeutics. Sponsors of clinical studies using investigational devices are required to comply with FDA's investigational device exemption regulations. Once approved or cleared, the sponsor of the device component submission (or the combination product submission, if both components are covered by one premarket submission) would need to comply with FDA's post-market device requirements, including establishment registration, device listing, device labeling, unique device identifier, quality system regulations, medical device reporting, and reporting of corrections and removals.

BLA submission, review by the FDA, and marketing approval

Assuming successful completion of the required clinical and preclinical testing, the results of product development, including chemistry, manufacture, and controls, non-clinical studies, and clinical trial results, including negative or ambiguous results as well as positive findings, are all submitted to the FDA, along with the proposed labeling, as part of a BLA requesting approval to market the product for one or more indications. In most cases, the submission of a BLA is subject to a substantial application user fee. These user fees must be paid at the time of the first submission of the application, even if the application is being submitted on a rolling basis. Fee waivers or reductions are available in certain circumstances. One basis for a waiver of the application user fee is if the applicant employs fewer than 500 employees, including employees of affiliates, the applicant does not have an approved marketing application for a product that has been introduced or delivered for introduction into interstate commerce, and the applicant, including its affiliates, is submitting its first marketing application.

In addition, under the Pediatric Research Equity Act, or PREA, a BLA or supplement to a BLA for a new active ingredient, indication, dosage form, dosage regimen, or route of administration, must contain data that are adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. Also, under the FDA Reauthorization Act of 2017, beginning in 2020, for applications for product candidates intended for the treatment of adult cancer which are directed at molecular targets that the FDA determines to be substantially relevant to the growth or progression of pediatric cancer, in place of the PREA investigations, sponsors must submit, with the application, reports from molecularly targeted pediatric cancer investigations designed to yield clinically meaningful pediatric study data, using appropriate formulations, to inform potential pediatric labeling. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements.

The FDA also may require submission of a REMS to ensure that the benefits of the biologic outweigh the risks. The REMS plan could include medication guides, physician communication plans, and elements to assure safe use, such as restricted distribution methods, patient registries, or other risk minimization tools. An assessment of the REMS must also be conducted at set intervals. Following product approval, a REMS may also be required by the FDA if new safety information is discovered and the FDA determines that a REMS is necessary to ensure that the benefits of the biologic outweigh the risks.

Once the FDA receives an application, it has 60 days to review the BLA to determine if it is substantially complete to permit a substantive review before it accepts the application for filing. The FDA may request additional information rather than accept a BLA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review.

Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA has set the review goal of completing its review of 90% of all applications within ten months from the 60-day filing date for its initial review of a BLA. This review goal is referred to as the PDUFA date. The PDUFA date is only a goal, thus, the FDA does not always meet its PDUFA dates. The review process and the PDUFA date may also be extended if the FDA requests or the sponsor otherwise provides substantial additional information or clarification regarding the submission.

The FDA may also refer certain applications to an advisory committee. Before approving a biologic for which no active ingredient, including any ester or salt of active ingredients, has previously been approved by the FDA, the FDA must either refer that biologic to an external advisory committee or provide in an action letter, a summary of the reasons why the FDA did not refer the product candidate to an advisory committee. An advisory committee is typically a panel that includes clinicians and other experts, which review, evaluate, and make a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

The FDA reviews applications to determine, among other things, whether a product is safe, pure and potent and whether the manufacturing methods and controls are adequate to assure and preserve the product's identity, strength, quality, potency, and purity. Before approving a BLA, the FDA typically will inspect the facility or facilities where the product is manufactured, referred to as a Pre-Approval Inspection. The FDA will not approve an application unless it determines that the manufacturing processes and facilities, including contract manufacturers and subcontractors, are in compliance with current cGMP requirements and adequate to assure consistent production of the

product within required specifications. Additionally, before approving a BLA the FDA will inspect one or more clinical trial sites to assure compliance with GCPs.

After evaluating the BLA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a Complete Response Letter, or CRL. A CRL indicates that the review cycle of the application is complete and the application is not ready for approval, and describes all of the specific deficiencies that the FDA identified in the BLA. A CRL generally contains a statement of specific conditions that must be met in order to secure final approval of the BLA and may require additional clinical or preclinical testing in order for the FDA to reconsider the application. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. If a CRL is issued, the applicant may either: resubmit the BLA, addressing all of the deficiencies identified in the letter; withdraw the application; or request an opportunity for a hearing. The FDA has the goal of reviewing 90% of application resubmissions in either two or six months of the resubmission date, depending on the kind of resubmission. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA may issue an approval letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications.

Even if the FDA approves a product, it may limit the approved indications or populations for use of the product, require that contraindications, warnings, or precautions be included in the product labeling, including a boxed warning, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a product's safety and efficacy after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms under a REMS which can materially affect the potential market and profitability of the product. The FDA may also not approve label statements that are necessary for successful commercialization and marketing.

After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval. The FDA may also withdraw the product approval if compliance with the pre- and post-marketing regulatory standards are not maintained or if problems occur after the product reaches the marketplace. Further, should new safety information arise, additional testing, product labeling, or FDA notification may be required.

Broadly equivalent requirements and controls similarly apply to the submission of pediatric testing and marketing authorization applications to the European Medicines Agency in the European Union and, post-approval, to the holding of such marketing authorizations, including conditionality.

Biosimilars and exclusivity

The BPCIA creates an abbreviated approval pathway for biological products shown to be highly similar to or interchangeable with an FDA-licensed reference biological product. Biosimilarity sufficient to reference a prior FDA-approved product requires a high similarity to the reference product notwithstanding minor differences in clinically inactive components, and no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency. Biosimilarity must be shown through analytical studies, animal studies, and at least one clinical trial, absent a waiver by the FDA. There must be no difference between the reference product and a biosimilar in mechanism of action, conditions of use, route of administration, dosage form, and strength. A biosimilar product may be deemed interchangeable with a prior approved product if it meets the higher hurdle of demonstrating that it can be expected to produce the same clinical results as

the reference product and, for products administered multiple times, the biosimilar and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. The FDA has issued a number of guidance documents outlining its approach to review and approval of biosimilars, including guidance documents on the demonstration of interchangeability and the licensure of biosimilar and interchangeable products for fewer than all of the reference product's licensed conditions of use.

A reference biologic is granted 12 years of exclusivity from the time of first licensure of the reference product, and no application for a biosimilar can be submitted for four years from the date of licensure of the reference product. However, certain changes and supplements to an approved BLA, and subsequent applications filed by the same sponsor, manufacturer, licensor, predecessor in interest, or other related entity do not qualify for the twelve-year exclusivity period. The PHSA also includes provisions to protect reference products that have patent protection. The biosimilar product sponsor and reference product sponsor may exchange certain patent and product information for the purpose of determining whether there should be a legal patent challenge. Based on the outcome of negotiations surrounding the exchanged information, the reference product sponsor may bring a patent infringement suit and injunction proceedings against the biosimilar product sponsor. The biosimilar applicant may also be able to bring an action for declaratory judgment concerning the patent.

In the European Union there is a period of 10 years (or 11 years for significant new indications) of data exclusivity so that those seeking to market biosimilars cannot apply on an abridged basis for a marketing authorization for eight years from when the product was first marketed in the European Union and cannot place it on the market for 10 or 11 years from such first marketing.

If approved, biologics may also be eligible for periods of United States patent term restoration. If granted, patent term restoration extends the patent life of a single unexpired patent, that has not previously been extended, for a maximum of five years. The total patent life with the extension also cannot exceed fourteen years from the product's approval date. Subject to the prior limitations, the period of the extension is calculated by adding half of the time from the effective date of an IND to the initial submission of a marketing application, and all of the time between the submission of the marketing application and its approval. This period may also be reduced by any time that the applicant did not act with due diligence.

In the European Union, a supplementary protection certificate, or SPC, can similarly extend a patent term for a maximum of five years. A six-month additional extension, however, is available if the SPC relates to a medicinal product for which data has been submitted according to a Pediatric Investigation Plan.

In an effort to increase competition in the biologic product marketplace, Congress, the executive branch, and FDA have taken certain legislative and regulatory steps. By way of example, in 2019 the FDA introduced a draft guidance to facilitate biologic product importation. Moreover, the 2020 Further Consolidated Appropriations Act included provisions requiring that sponsors of approved biologic products, including those subject to REMS, provide samples of the approved products to persons developing biosimilar products within specified timeframes, in sufficient quantities, and on commercially reasonable market-based terms. Failure to do so can subject the approved product sponsor to civil actions, penalties, and responsibility for attorney's fees and costs of the civil action.

Post-approval requirements

Any products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements related to manufacturing, recordkeeping, and reporting, including adverse experience reporting, deviation reporting, shortage reporting, risk management plans, supply chain security, and periodic reporting, product distribution, advertising, marketing, promotion, certain electronic records and signatures, and post-approval obligations imposed as a condition of approval, such as Phase 4 clinical trials, REMS, and surveillance to assess safety and effectiveness after commercialization.

After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There also are continuing annual program user fee requirements for approved products. In addition, manufacturers and other entities involved in the manufacture and distribution of approved therapeutics are required to register their establishments with the FDA and certain state agencies, list their products, and are subject to periodic announced and unannounced inspections by the FDA and these state agencies for compliance with current cGMP and other requirements, which impose certain procedural and documentation requirements upon us and third-party manufacturers. Manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with current cGMPs. Regulatory authorities may withdraw product approvals, require label modifications or request product recalls, among other actions, if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

Changes to the manufacturing process are strictly regulated and often require prior FDA approval or notification before being implemented. FDA regulations also require investigation and correction of any deviations from current cGMP and specifications and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain current cGMP compliance.

The FDA also strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the market. A company can make only those claims relating to safety and efficacy, purity, and potency that are approved by the FDA. Physicians, in their independent professional medical judgment, may prescribe legally available products for unapproved indications that are not described in the product's labeling and that differ from those tested and approved by the FDA. Biopharmaceutical companies, however, are required to promote their products only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including, but not limited to, criminal and civil penalties under the FDCA and False Claims Act, exclusion from participation in federal healthcare programs, mandatory compliance programs under corporate integrity agreements, suspension and debarment from government contracts, and refusal of orders under existing government contracts.

Moreover, the Drug Quality and Security Act imposes obligations on manufacturers of biopharmaceutical products related to product tracking and tracing. Among the requirements of this legislation, manufacturers are required to provide certain information regarding the products to individuals and entities to which product ownership is transferred, are required to label products with a product identifier, and are required to keep certain records regarding the product. The transfer of information to subsequent product owners by manufacturers is also required to be done electronically. Manufacturers must also verify that purchasers of the manufacturers' products are appropriately licensed. Further, under this legislation, manufactures have product investigation, quarantine, disposition, and notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products that would result in serious adverse health consequences or death to humans, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death. Similar requirements additionally are and will be imposed through this legislation on other companies within the biopharmaceutical product supply chain, such as distributors and dispensers.

Adverse event reporting and submission of periodic reports, including annual reports and deviation reports, are required following FDA approval of a BLA. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with

manufacturing processes, or failure to comply with regulatory requirements, may result in significant regulatory actions. Such actions may include refusal to approve pending applications, license suspension or revocation, imposition of a clinical hold or termination of clinical trials, warning letters, untitled letters, cyber letters, modification of promotional materials or labeling, provision of corrective information, imposition of post-market requirements including the need for additional testing, imposition of distribution or other restrictions under a REMS, product recalls, product seizures or detentions, refusal to allow imports or exports, total or partial suspension of production or distribution, FDA debarment, injunctions, fines, consent decrees, corporate integrity agreements, suspension and debarment from government contracts, refusal of orders under existing government contracts, exclusion from participation in federal and state healthcare programs, restitution, disgorgement, or civil or criminal penalties, including fines and imprisonment, and result in adverse publicity, among other adverse consequences.

Broadly equivalent requirements, controls and sanctions similarly apply to supply, QA, manufacture, labelling, advertising, pharmacovigilance and tracing of medicinal products as imposed by EU laws and enforced by EU national regulatory authorities.

Additional controls for biologics

To help reduce the increased risk of the introduction of adventitious agents, the PHSA emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined. The PHSA also provides authority to the FDA to immediately suspend licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases in the United States and between states.

After a BLA is approved, the product may also be subject to official lot release as a condition of approval. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing the results of all of the manufacturer's tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some products before releasing the lots for distribution by the manufacturer.

In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products. There are also a number of additional standards that apply to oncolytic virus products. The FDA has issued various applicable guidance documents on factors that the agency considers during product development including, but not limited to, preclinical assessments; chemistry manufacturing and controls; and long-term patient and clinical study subject follow up and regulatory reporting. In the EU, the EMA issues scientific guidelines on biological medicinal products and the standard Common Technical Document structure is modified for biologicals, plasma-derived products.

Fraud and abuse, data privacy and security, and transparency laws and regulations

Our business activities, including but not limited to, research, sales, promotion, distribution, medical education, and other activities following product approval will be subject to regulation by numerous federal and state regulatory and law enforcement authorities in the United States in addition to the FDA, including potentially the Department of Justice, the Department of Health and Human Services and its various divisions, including the CMS and the Health Resources and Services Administration, the Department of Veterans Affairs, the Department of Defense, and state and local governments. Our business activities must comply with numerous healthcare laws, including but not limited to, anti-kickback and false claims laws and regulations as well as data privacy and security laws

and regulations, which are described below, as well as state and federal consumer protection and unfair competition laws.

The federal Anti-Kickback Statute, which regulates, among other things, marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities, prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting, or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order, or the referral to another for the furnishing or arranging for the furnishing of any item or service reimbursable under Medicare, Medicaid, or other federal healthcare programs, in whole or in part. The term "remuneration" has been interpreted broadly to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between biopharmaceutical manufacturers on one hand and prescribers, purchasers, formulary managers, and beneficiaries on the other, as well as free trial and starter prescriptions provided through pharmacies. There are certain statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly, and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of the facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, including purchases of products paid by federal healthcare programs, the statute has been violated. The ACA modified the intent requirement under the Anti-Kickback Statute to a stricter standard, such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the ACA also provided that a violation of the federal Anti-Kickback Statute is grounds for the government or a whistleblower to assert that a claim for payment of items or services resulting from such violation constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

The federal civil False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to, or approval by, the federal government, knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government, or avoiding, decreasing, or concealing an obligation to pay money to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. The civil False Claims Act has been used to assert liability on the basis of kickbacks and other improper referrals, improperly reported government pricing metrics such as Best Price or Average Manufacturer Price, improper use of Medicare provider or supplier numbers when detailing a provider of services, improper promotion of off-label uses not expressly approved by the FDA in a product's label, and allegations as to misrepresentations with respect to products, contract requirements and services rendered. In addition, private payers have filed follow-on lawsuits alleging fraudulent misrepresentation, although establishing liability and damages in these cases is more difficult than under the civil False Claims Act. Intent to deceive is not required to establish liability under the civil False Claims Act. Civil False Claims Act actions may be brought by the government or may be brought by private individuals on behalf of the government, called "qui tam" actions. If the government decides to intervene in a qui tam action and prevails in the lawsuit, the individual will share in the proceeds from any fines or settlement funds. If the government declines to intervene, the individual may pursue the case alone. The civil False Claims Act provides for treble damages and a civil penalty for each false claim, such as an invoice or pharmacy claim for reimbursement, which can aggregate into millions of dollars. For these reasons, since 2004, civil False Claims Act lawsuits against biopharmaceutical companies have increased significantly in

volume and breadth, leading to several substantial civil and criminal settlements, as much as $3.0 billion, regarding certain sales practices and promoting off label uses. Civil False Claims Act liability may further be imposed for known Medicare or Medicaid overpayments, for example, overpayments caused by understated rebate amounts, that are not refunded within 60 days of discovering the overpayment, even if the overpayment was not caused by a false or fraudulent act. In addition, conviction or civil judgment for violating the civil False Claims Act may result in exclusion from federal health care programs, and suspension and debarment from government contracts, and refusal of orders under existing government contracts.

The government may further prosecute conduct constituting a false claim under the criminal False Claims Act. The criminal False Claims Act prohibits the making or presenting of a claim to the government knowing such claim to be false, fictitious, or fraudulent and, unlike the civil False Claims Act, requires proof of intent to submit a false claim.

The civil monetary penalties statute is another potential statute under which biopharmaceutical companies may be subject to enforcement. Among other things, the civil monetary penalties statute imposes fines against any person who is determined to have knowingly presented, or caused to be presented, claims to a federal healthcare program that the person knows, or should know, is for an item or service that was not provided as claimed or is false or fraudulent.

Payment or reimbursement of prescription therapeutics by Medicaid or Medicare requires manufacturers to submit certified pricing information to CMS. The Medicaid Drug Rebate statute requires manufacturers to calculate and report price points, which are used to determine Medicaid rebate payments shared between the states and the federal government and Medicaid payment rates for certain therapeutics. The Medicaid Drug Rebate statute also imposes inflation penalties, and recent legislative proposals have called for removal of caps limiting the magnitude of these penalties and the implementation of new inflation penalties applicable to the Medicare program. In addition to the Medicaid statutory rebate, states are authorized to negotiate supplemental rebates on pharmaceuticals included in their formularies. For therapeutics paid under Medicare Part B, manufacturers must also calculate and report their Average Sales Price, which is used to determine the Medicare Part B payment rate. In addition, therapeutics covered by Medicaid are subject to an additional inflation penalty which can substantially increase rebate payments. For products approved under a BLA (including biosimilars), or an NDA, the Veterans Health Care Act, or VHCA, requires manufacturers to calculate and report to the Veterans Administration, or VA, a different price called the Non-Federal Average Manufacturing Price, which is used to determine the maximum price that can be charged to certain federal agencies, referred to as the Federal Ceiling Price, or FCP. Like the Medicaid rebate amount, the FCP includes an inflation penalty. A Department of Defense regulation requires manufacturers to provide this discount on therapeutics dispensed by retail pharmacies when paid by the TRICARE Program. All of these price reporting requirements create risk of submitting false information to the government, and potential FCA liability.

The VHCA also requires manufacturers of covered therapeutics participating in the Medicaid program to enter into Federal Supply Schedule contracts with the VA through which their covered therapeutics must be sold to certain federal agencies at FCP. This necessitates compliance with applicable federal procurement laws and regulations, including submission of commercial sales and pricing information and certification of compliance with the Trade Agreements Act, and subjects us to contractual remedies as well as administrative, civil, and criminal sanctions. In addition, the VHCA requires manufacturers participating in Medicaid to agree to provide different mandatory discounts to certain Public Health Service grantees and other safety net hospitals and clinics under the 340B program based on the manufacturer's reported Medicaid pricing information. The 340B program has its own regulatory authority to impose sanctions for non-compliance and adjudicate overcharge claims against manufacturers by the purchasing entities.

The federal Health Insurance Portability and Accountability Act of 1996, as amended, or HIPAA, also created federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, a healthcare benefit program, regardless of whether the payor is public or private, in connection with the delivery or payment for health care benefits, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing, or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items, or services relating to healthcare matters. Additionally, the ACA amended the intent requirement of certain of these criminal statutes under HIPAA so that a person or entity no longer needs to have actual knowledge of the statute, or the specific intent to violate it, to have committed a violation.

The ACA further created new federal requirements for reporting, by applicable manufacturers of covered therapeutics, payments and other transfers of value to persons and entities such as physicians and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members.

Further, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by HITECH, and its respective implementing regulations imposes certain requirements on covered entities relating to the privacy, security, and transmission of certain individually identifiable health information known as protected health information. Among other things, HITECH, through its implementing regulations, makes HIPAA's security standards and certain privacy standards directly applicable to business associates, defined as a person or organization, other than a member of a covered entity's workforce, that creates, receives, maintains, or transmits protected health information on behalf of a covered entity for a function or activity regulated by HIPAA. HITECH also strengthened the civil and criminal penalties that may be imposed against covered entities, business associates, and individuals, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, other federal and state laws, such as the California Consumer Privacy Act, may govern the privacy and security of health and other information in certain circumstances, many of which differ from each other in significant ways and may not be preempted by HIPAA, thus complicating compliance efforts.

Many states have also adopted laws similar to each of the above federal laws, which may be broader in scope and apply to items or services reimbursed by any third-party payor, including commercial insurers. Certain state laws also regulate manufacturers' use of prescriber-identifiable data. Certain states also require implementation of commercial compliance programs and compliance with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments or the provision of other items of value that may be made to healthcare providers and other potential referral sources; impose restrictions on marketing practices; or require manufacturers to track and report information related to payments, gifts, and other items of value to physicians and other healthcare providers. Recently, states have enacted or are considering legislation intended to make drug prices more transparent and deter significant price increases. These laws may affect our future sales, marketing, and other promotional activities by imposing administrative and compliance burdens.

If our operations are found to be in violation of any of the laws or regulations described above or any other laws that apply to us, we may be subject penalties or other enforcement actions, including criminal and significant civil monetary penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, corporate integrity agreements, suspension and

debarment from government contracts, and refusal of orders under existing government contracts, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals. In the European Union, the data privacy laws are generally perceived to be stricter than those which apply in the United States and include specific requirements for the transfer of personal data outside the European Union to the United States to ensure that European Union standards of data privacy will be applied to such data.

Coverage and reimbursement generally

The commercial success of our product candidates and our ability to commercialize any approved product candidates successfully will depend in part on the extent to which governmental payor programs at the federal and state levels, including Medicare and Medicaid, private health insurers, and other third-party payors, provide coverage for and establish adequate reimbursement levels for our product candidates. Government authorities, private health insurers, and other organizations generally decide which therapeutics they will pay for and establish reimbursement levels for healthcare. Medicare is a federally funded program managed by CMS through local fiscal intermediaries and carriers that administer coverage and reimbursement for certain healthcare items and services furnished to the elderly and disabled. Medicaid is an insurance program for certain categories of patients whose income and assets fall below state defined levels and who are otherwise uninsured that is both federally and state funded and managed by each state. The federal government sets general guidelines for Medicaid and each state creates specific regulations that govern its individual program, including supplemental rebate programs that restrict coverage to therapeutics on the state Preferred Drug List. Similarly, government laws and regulations establish the parameters for coverage of prescription therapeutics by health plans participating in state exchanges and Tricare, the health care program for military personnel, retirees, and related beneficiaries. Some states have also created pharmacy assistance programs for individuals who do not qualify for federal programs. In the United States, private health insurers and other third-party payors often provide reimbursement for products and services based on the level at which the government provides reimbursement through the Medicare or Medicaid programs for such products and services.

In the United States, the European Union, and other potentially significant markets for our product candidates, government authorities and third-party payors are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which often has resulted in average selling prices lower than they would otherwise be and sometimes at or below the provider's acquisition cost. In the United States, it is also common for government and private health plans to use coverage determinations to leverage rebates from manufacturers in order to reduce the plans' net costs. These restrictions and limitations influence the purchase of healthcare services and products and lower the realization on manufacturers' sales of prescription therapeutics. Third-party payors are developing increasingly sophisticated methods of controlling healthcare costs. Third-party payors may limit coverage to specific therapeutic products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication or might impose high copayment amounts to influence patient choice. Third-party payors also control costs by requiring prior authorization or imposing other dispensing restrictions before covering certain products and by broadening therapeutic classes to increase competition. Third-party payors are increasingly challenging the price and examining the medical necessity and

cost-effectiveness of medical products and services, in addition to their safety and efficacy. Absent clinical differentiators, third-party payors may treat products as therapeutically equivalent and base formulary decisions on net cost. To lower the prescription cost, manufacturers frequently rebate a portion of the prescription price to the third-party payors. Recently, purchasers and third-party payors have begun to focus on value of new therapeutics and sought agreements in which price is based on achievement of performance metrics.

Federal programs also impose price controls through mandatory ceiling prices on purchases by federal agencies and federally funded hospitals and clinics and mandatory rebates on retail pharmacy prescriptions paid by Medicaid and Tricare. These restrictions and limitations influence the purchase of healthcare services and products. Legislative proposals to reform healthcare or reduce costs under government programs may result in lower reimbursement for our product candidates or exclusion of our product candidates from coverage. In addition, government programs like Medicaid include substantial penalties for increasing commercial prices over the rate of inflation which can affect realization and return on investment.

Private payors often rely on the lead of the governmental payors in rendering coverage and reimbursement determinations. Therefore, achieving favorable CMS coverage and reimbursement is usually a significant gating issue for successful introduction of a new product. In addition, many government programs as a condition of participation mandate fixed discounts or rebates from manufacturers regardless of formulary position or utilization, and then rely on competition in the market to attain further price reductions, which can greatly reduce realization on the sale.

Further, the increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in the European Union will put additional pressure on product pricing, reimbursement, and utilization, which may adversely affect our future product sales and results of operations. These pressures can arise from rules and practices of managed care groups, competition within therapeutic classes, judicial decisions and governmental laws and regulations related to Medicare, Medicaid, and healthcare reform, biopharmaceutical coverage and reimbursement policies, and pricing in general. Patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Sales of our product candidates will therefore depend substantially, both domestically and abroad, on the extent to which the costs of our products will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, such as Medicare and Medicaid, private health insurers, and other third-party payors.

As a result of the above, we may need to conduct expensive pharmacoeconomic and/or health technology assessment studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain the FDA and EMA approvals. Our product candidates may not be considered medically necessary or cost-effective, or the rebate percentages required to secure coverage may not yield an adequate margin over cost.

Moreover, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in therapeutic development. Legislative proposals to reform healthcare or reduce costs under government insurance programs may result in lower reimbursement for our products and product candidates or exclusion of our products and product candidates from coverage. The cost containment measures that healthcare payors and providers are instituting and any healthcare reform could significantly reduce our revenues from the sale of any approved product candidates. We cannot provide any assurances that we will be able to obtain and maintain third-party coverage or adequate reimbursement for our product candidates in whole or in part.

The absence in Europe of any substantive harmonization of pricing and reimbursement regimes, including health technology assessment, means that separate negotiations will need to take place with the relevant authorities in each member state and may include a variety of risk share agreements with payors.

Healthcare reform measures

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals designed to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality, and expanding access. In the United States, the biopharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

For example, Medicare Part B, which covers products administered by physicians in an outpatient setting, may be undergoing a significant change in payment rates. In October 2018, CMS issued an advance notice of proposed rulemaking paving the way for a proposed rule that would significantly reduce the price of drugs paid by Medicare Part B by basing reimbursement on the average prices among other industrialized countries. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors.

Moreover, the ACA broadened access to health insurance, attempts to reduce or constrain the growth of healthcare spending, enhanced remedies against fraud and abuse, added new transparency requirements for healthcare and health insurance industries, imposed new taxes and fees on the health care industry, and imposed additional health policy reforms. The law expanded the eligibility criteria and mandatory eligibility categories for Medicaid programs, thereby potentially increasing both the volume of sales and manufacturers' Medicaid rebate liability. The law also expanded the 340B discount program that mandates discounts to certain hospitals, community centers, and other qualifying providers, by expanding the categories of entities eligible to purchase under the program. In addition, the ACA authorized civil monetary penalties for violating 340B pricing requirements, and regulations implementing this authority became effective on January 1, 2019. The ACA revised the definition of "average manufacturer price", or AMP, for reporting purposes, which generally increased the amount of Medicaid rebates to states and created a separate AMP for certain categories of administered therapeutics provided in non-retail outpatient settings. The law additionally extended manufacturer's Medicaid rebate liability to covered therapeutics dispensed to patients enrolled in Medicaid managed care organizations and increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate program. The revisions to the AMP definition and Medicaid rebate formula can have the further effect of increasing the required 340B discounts. Further, the ACA requires manufacturers of therapeutics to pay 50% of the pharmacy charge to Medicare Part D patients while they are in the coverage gap, and this percentage was increased to 70% by the Bipartisan Budget Act of 2018. Finally, the ACA imposes a significant annual fee on companies that manufacture or import branded prescription therapeutic products. Substantial new provisions affecting compliance have also been enacted through the ACA and otherwise, including the reporting of therapeutic sample distribution, which may require us to modify our business practices with healthcare practitioners. Although the ACA was recently amended to repeal the individual insurance mandate, and efforts to repeal and replace portions of the law may continue, it is likely that pressure on biopharmaceutical pricing, especially under the Medicare program, will continue, and may also increase our regulatory burdens and operating costs. Moreover, in the coming years, additional changes could be made to governmental healthcare programs that could significantly impact the success of our product candidates.

The cost of biopharmaceuticals continues to generate substantial governmental and third-party payor interest. We expect that the biopharmaceutical industry will experience pricing pressures due to

the trend toward managed healthcare, the increasing influence of managed care organizations and additional legislative proposals. Our results of operations could be adversely affected by current and future healthcare reforms.

Some third-party payors also require pre-approval of coverage for new or innovative devices or therapies before they will reimburse healthcare providers that use such therapies. While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, the announcement or adoption of these proposals could have a material adverse effect on our ability to obtain adequate prices for our product candidates.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. The Budget Control Act of 2011, as amended, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee on Deficit Reduction did not achieve its targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reductions to several government programs. These reductions include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year. The Bipartisan Budget Act of 2018 retained the federal budget "sequestration" Medicare payment reductions of 2%, and extended it through 2027. The American Taxpayer Relief Act of 2012 further reduced Medicare payments to several categories of healthcare providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These and other healthcare reform initiatives may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our financial operations. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could further limit the prices we are able to charge, or the amounts of reimbursement available, for our product candidates once they are approved. The Bipartisan Budget Act also extended Manufacturer responsibility for prescription costs in the Medicare Part D coverage gap to biosimilars, which had previously been exempt.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party, or candidate or representatives of international organizations for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business or obtaining an improper advantage. The FCPA also obligates companies whose securities are listed in the United States to comply with books and records an accounting control provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. Activities that violate the FCPA, even if they occur wholly outside the United States, can result in criminal and civil fines, imprisonment, disgorgement, oversight by compliance monitors, and suspension and debarment from government contracts, and refusal of orders under existing government contracts.

Other foreign anti-corruption regimes are arguably of wider application. For instance, the U.K. Bribery Act 2010 applies to dealings with any decision maker whether in the private or public sector in a position of trust.

Background on certain of our target indications

Set forth below is a description of certain of the target indications we currently intend to pursue with our product candidates.

Cutaneous squamous cell carcinoma

CSCC is the second most common form of skin cancer and is estimated to be responsible for at least 7,000 deaths each year in the United States. It currently accounts for approximately 20% of all skin cancers in the U.S., with the number of newly diagnosed cases expected to rise annually. When CSCC invades deeper layers of the skin or adjacent tissues, it is categorized as locally advanced. Once it spreads to other distant parts of the body, it is considered metastatic. Cemiplimab is the only approved therapy in the United States and Brazil, and conditionally approved therapy in the European Union and Canada, for the treatment of locally advanced or metastatic CSCC.

Melanoma

Melanoma is a form of skin cancer characterized by the uncontrolled growth of pigment-producing cells (melanocytes) located in the skin. Metastatic melanoma is the deadliest form of the disease and occurs when cancer spreads beyond the surface of the skin to other organs. The incidence of melanoma has been increasing steadily for the last 30 years. In the United States, 91,270 new diagnoses of melanoma and more than 9,320 related deaths were estimated to have occurred in 2018. Globally, the World Health Organization estimates that by 2035, melanoma incidence will reach 424,102, with 94,308 related deaths. Melanoma is mostly curable when treated in its very early stages; however, survival rates are roughly halved if regional lymph nodes are involved.

Employees

As of March 31, 2020, we had 122 full-time employees.

Corporate information

We are a Delaware corporation organized in July 2017. Our principal executive offices are located at 500 Unicorn Park, Woburn, MA 01801, and our telephone number is (781) 222-9600. Our website is www.replimune.com. Information that is contained on, or that can be accessed through, our website is not incorporated by reference into this Annual Report on Form 10-K, and you should not consider information on our website to be part of this Annual Report on Form 10-K.

Available information

We make available free of charge on the investor relations portion of our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, Proxy Statements for our annual meetings of stockholders, and amendments to those reports, as soon as reasonably practicable after we file such material with, or furnish it to,Ì the Securities and Exchange Commission, or SEC. These filings are available for download free of charge on the investor relations portion of our website located at https://ir.replimune.com. The SEC also maintains a website that contains reports, proxy and information statements and other information about issuers, like us, that file electronically with the SEC. The address of that website is https://www.sec.gov.

Item 1A. Risk factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this Annual Report on Form 10-K, including our audited consolidated financial statements and related notes and "Management's discussion and analysis of results of operations and financial condition." If any of the following risks are realized, our business, financial condition, operating results and prospects could be materially and adversely affected. In that event, the price of our common stock could decline, and you could lose part or all of your investment. The risks and uncertainties described below are not the only ones we face. Additional risks and

uncertainties not presently known to us or that we currently believe to be immaterial may also adversely affect our business.

Risks related to product development

Our product candidates are in the early stages of development, are not approved for commercial sale and might never receive regulatory approval or become commercially viable. We have never generated any revenue from product sales and may never be profitable.

All of our product candidates are in research or early development. We have not generated any revenues from the sale of products and do not expect to do so for at least the next several years. Our lead product candidate, RP1, and any other product candidates will require extensive preclinical and/or clinical testing and regulatory approval prior to commercial use. Our research and development efforts may not be successful. Even if our clinical development efforts result in positive data, our product candidates may not receive regulatory approval or be successfully introduced and marketed at prices that would permit us to operate profitably.

We currently have only two product candidates in clinical development. A failure of these product candidates in clinical development would adversely affect our business and may require us to discontinue development of other product candidates based on the same or similar therapeutic approaches.

RP1 and RP2 are our only clinical development-stage product candidates. Although we have another product candidate, RP3, in preclinical development and we may develop additional product candidates in the coming years, it will take additional investment and time for such product candidates to reach the same stage of development as those that are in clinical development, and there can be no assurance that they will ever do so. Since all of the product candidates in our current pipeline are based on our Immulytic platform, if RP1 fails in development as a result of any underlying problem with our Immulytic platform, then we may be required to discontinue development of all product candidates that are based on our therapeutic approach. If we were required to discontinue development of RP1, RP2 or our other product candidates, or if any of them were to fail to receive regulatory approval or achieve sufficient market acceptance, we could be prevented from or significantly delayed in achieving profitability. We can provide no assurance that we would be successful at developing other product candidates based on an alternative therapeutic approach.

We will not be able to commercialize our product candidates if our preclinical studies do not produce successful results and/or our clinical trials do not demonstrate the safety and efficacy of our product candidates.

Our lead product candidate, RP1, is in an ongoing Phase 1/2 clinical trial alone and in combination with nivolumab and we have initiated a Phase 2 clinical trial of RP1 in combination with cemiplimab in CSCC. We have also opened for enrollment a Phase 1b clinical trial of single agent RP1 in solid organ transplant recipients in approximately 30 patients with CSCC. Additionally, RP2, the next product candidate from our Immulytic platform, is in an ongoing Phase 1/2 clinical trial alone and in combination with nivolumab. Our third product candidate, RP3, is in preclinical development. We expect to enter clinical development in 2020. Our product candidates will require preclinical and/or clinical trials before we can submit a marketing application to the applicable regulatory authorities.

Our product candidates are susceptible to the risks of failure inherent at any stage of product development, including the occurrence of unexpected or unacceptable adverse events or the failure to demonstrate efficacy in clinical trials. Clinical development is expensive and can take many years to complete, and its outcome is inherently uncertain.

The results of preclinical studies, preliminary study results, and early clinical trials of our product candidates may not be predictive of the results of later stage clinical trials. Our product candidates may

not perform as we expect, may ultimately have a different or no impact on tumors, may have a different mechanism of action than we expect in humans, and may not ultimately prove to be safe and effective.

Preliminary and final results from preclinical studies and early stage trials, and trials in compounds that we believe are similar to ours, may not be representative of results that are found in larger, controlled, blinded, and longer-term studies. Product candidates may fail at any stage of preclinical or clinical development. Product candidates may fail to show the desired safety and efficacy traits even if they have progressed through preclinical studies or initial clinical trials. Preclinical studies and clinical trials may also reveal unfavorable product candidate characteristics, including safety concerns. A number of companies in the biopharmaceutical industry have suffered significant setbacks in clinical trials, notwithstanding promising results in earlier preclinical studies or clinical trials or promising mechanisms of action. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. Moreover, should there be an issue with the design of a clinical trial, our results may be impacted. We may not discover such a flaw until the clinical trial is at an advanced stage.

We may also experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- regulators or institutional review boards, or IRBs, may not authorize us or our investigators to commence a clinical trial, conduct a clinical trial at a prospective trial site, or amend trial protocols, or may require that we modify or amend our clinical trial protocols;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites and/or contract research organizations, or CROs;
- clinical trials of our product candidates may produce negative or inconclusive results, or our studies may fail to reach the necessary level of statistical significance, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials or be lost to follow-up at a higher rate than we anticipate, or may elect to participate in alternative clinical trials sponsored by our competitors with product candidates that treat the same indications as our product candidates;
- our third-party contractors may fail to comply with regulatory requirements or the clinical trial protocol, or meet their contractual obligations to us in a timely manner, or at all, or we may be required to engage in additional clinical trial site monitoring;
- we, regulators, or IRBs may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks, undesirable side effects, or other unexpected characteristics of the product candidate, or due to findings of undesirable effects caused by a chemically or mechanistically similar therapeutic or therapeutic candidate;
- changes could be adopted in marketing approval policies during the development period, rendering our data insufficient to obtain marketing approval;

- statutes or regulations could be amended or new ones could be adopted;
- changes could be adopted in the regulatory review process for submitted product applications;
- the cost of clinical trials of our product candidates may be greater than we anticipate or we may have insufficient funds for a clinical trial or to pay the substantial user fees required by the FDA upon the filing of a Biologics License Application, or BLA, or equivalent authorizations from comparable foreign regulatory authorities;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- we may decide, or regulators may require us, to conduct or gather, as applicable, additional clinical trials, analyses, reports, data, or preclinical trials, or we may abandon product development programs;
- we may fail to reach an agreement with regulators or IRBs regarding the scope, design, or implementation of our clinical trials, and the FDA or comparable foreign regulatory authorities may require changes to our study designs that make further study impractical or not financially prudent;
- regulators may ultimately disagree with the design or our conduct of our preclinical studies or clinical trials, finding that they do not support product candidate approval;
- we may have delays in adding new investigators or clinical trial sites, or we may experience a withdrawal of clinical trial sites;
- patients that enroll in our studies may misrepresent their eligibility or may otherwise not comply with the clinical trial protocol, resulting in the need to drop the patients from the study or clinical trial, increase the needed enrollment size for the clinical trial or extend its duration;
- there may be regulatory questions or disagreements regarding interpretations of data and results;
- the FDA or comparable foreign regulatory authorities may disagree with our study design, including endpoints, or our interpretation of data from preclinical studies and clinical trials or find that a product candidate's benefits do not outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may not accept data from studies with clinical trial sites in foreign countries;
- the FDA or comparable foreign regulatory authorities may disagree with our intended indications;
- the FDA or comparable foreign regulatory authorities may fail to approve or subsequently find fault with the manufacturing processes or our manufacturing facilities for clinical and future commercial supplies;
- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of a BLA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may take longer than we anticipate to make a decision on our product candidates;
- we may not be able to demonstrate that a product candidate provides an advantage over current standards of care or current or future competitive therapies in development; and

- we, the third parties on which we rely, and the FDA may have delays in the conduct of our respective operations as a result of the effects of the COVID-19 pandemic, which could result in delays or prevent our ability to receive marketing approval or commercialize our product candidates.

Our development costs will also increase if we experience delays in testing or approvals, and we may not have sufficient funding to complete the testing and approval process for any of our product candidates. We may be required to obtain additional funds to complete clinical trials and prepare for possible commercialization of our product candidates. We do not know whether any preclinical tests or clinical trials beyond what we currently have planned will be required, will begin as planned, will need to be restructured, or will be completed on schedule, or at all. Significant delays relating to any preclinical or clinical trials also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations. In addition, many of the factors that cause, or lead to, delays in clinical trials may ultimately lead to the denial of marketing approval of any of our product candidates. If any of these occur, our business, financial condition, results of operations, stock price and prospects may be materially harmed.

We anticipate that our product candidates will be used in combination with third-party drugs, some of which are still in development, and we have limited or no control over the supply, regulatory status, or regulatory approval of such drugs.

Our product candidates may be administered in combination with checkpoint blockade drugs, a class of drugs that are intended to stop tumor cells from "switching off" an immune system attack against themselves. We have entered into agreements with BMS for the supply of nivolumab, its anti-PD-1 therapy, for use in connection with our current Phase 1/2 clinical trials with RP1 and RP2. We have also entered into a clinical collaboration agreement with Regeneron, which includes the supply of cemiplimab, its anti-PD-1 therapy, for clinical trials conducted thereunder. We are enrolling patients in our first planned clinical trial under the Regeneron agreement, a randomized, controlled Phase 2 clinical trial of RP1 in combination with cemiplimab, versus cemiplimab alone, in approximately 240 patients with CSCC. We may enter into additional agreements for the supply of anti-PD-1 products for use in connection with the development of one or more of our product candidates. Our ability to develop and ultimately commercialize our product candidates used in combination with nivolumab, cemiplimab or any other checkpoint blockade therapy will depend on our ability to access such drugs on commercially reasonable terms for the clinical trials and their availability for use with the commercialized product, if approved. We cannot be certain that current or potential future commercial relationships will provide us with a steady supply of such drugs on commercially reasonable terms or at all.

Any failure to maintain or enter into new successful commercial relationships, or the expense of purchasing checkpoint blockade therapies in the market, may delay our development timelines, increase our costs and jeopardize our ability to develop our product candidates as commercially viable therapies. If any of these occur, our business, financial condition, results of operations, stock price and prospects may be materially harmed.

Moreover, the development of product candidates for use in combination with another product or product candidate may present challenges that are not faced for single agent product candidates. While we are planning a new clinical trial for use of RP1 as a monotherapy, we are developing RP1 and our other product candidates for use in combination with anti-PD-1 or anti-PDL1 therapies and may develop RP1 or our other product candidates for use with other therapies. The FDA may require us to use more complex clinical trial designs in order to evaluate the contribution of each product and product candidate to any observed effects. It is possible that the results of these trials could show that

any positive previous trial results are attributable to the combination therapy and not our product candidates. Moreover, following product approval, the FDA may require that products used in conjunction with each other be cross-labeled for combined use. To the extent that we do not have rights to the other product, this may require us to work with a third party to satisfy such a requirement. Moreover, developments related to the other product may impact our clinical trials for the combination as well as our commercial prospects should we receive marketing approval. Such developments may include changes to the other product's safety or efficacy profile, changes to the availability of the approved product, and changes to the standard of care.

In the event that BMS, Regeneron or any future collaborator or supplier cannot continue to supply their products on commercially reasonable terms, we would need to identify alternatives for accessing an anti-PD-1 therapy. Additionally, should the supply of products from BMS, Regeneron or any future collaborator or supplier be interrupted, delayed or otherwise be unavailable to us, our clinical trials may be delayed. In the event we are unable to source a supply of an alternative anti-PD-1 therapy, or are unable to do so on commercially reasonable terms, our business, financial condition, results of operations, stock price and prospects may be materially harmed.

If we fail to develop additional product candidates, our commercial opportunity could be limited.

Our lead product candidate is RP1. A key part of our strategy is to pursue clinical development of RP1 and additional product candidates, including RP2 and RP3. Developing, obtaining marketing approval for, and commercializing additional product candidates will require substantial additional funding and will be subject to the risks of failure inherent in medical product development. We cannot assure our shareholders that we will be able to successfully advance any of these additional product candidates through the development process.

Even if we obtain approval from the FDA or comparable foreign regulatory authorities to market additional product candidates for the treatment of solid tumors, we cannot assure our shareholders that any such product candidates will be successfully commercialized, widely accepted in the marketplace, or more effective than other commercially available alternatives. If we are unable to successfully develop and commercialize additional product candidates, our commercial opportunity may be limited and our business, financial condition, results of operations, stock price and prospects may be materially harmed.

Risks related to regulatory approval

Even if our development efforts are successful, we may not obtain regulatory approval for any of our product candidates in the United States or other jurisdictions, which would prevent us from commercializing our product candidates. Even if we obtain regulatory approval for our product candidates, any such approval may be subject to limitations, including with respect to the approved indications or patient populations, which could impair our ability to successfully commercialize our product candidates.

We are not permitted to market or promote or sell any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy for that indication. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities and clinical trial sites by, the regulatory authorities. If we do not receive approval from the FDA and comparable foreign regulatory authorities for any of our product candidates, we will not be able to commercialize such product candidates in the United States or in other jurisdictions. If significant delays in obtaining approval for and commercializing our product candidates occur in any jurisdictions, our business,

financial condition, results of operations, stock price and prospects will be materially harmed. Even if our product candidates are approved, they may:

- be subject to limitations on the indicated uses or patient populations for which they may be marketed, distribution restrictions, or other conditions of approval;
- contain significant safety warnings, including boxed warnings, contraindications, and precautions;
- not be approved with label statements necessary or desirable for successful commercialization; or
- contain requirements for costly postmarket testing and surveillance, or other requirements, including the submission of a risk evaluation and mitigation strategy, or REMS, to monitor the safety or efficacy of the products.

We have not previously submitted a BLA to the FDA, or a similar marketing application to comparable foreign regulatory authorities, for any product candidate, and we can provide no assurance that we will ultimately be successful in obtaining regulatory approval for claims that are necessary or desirable for successful marketing, or at all.

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are not able to obtain, or experience delays in obtaining, required regulatory approvals, we will not be able to commercialize our product candidates as expected, and our ability to generate revenue may be materially impaired.

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions and there may be varying interpretations of data obtained from preclinical studies or clinical trials, any of which may cause delays or limitations in the approval or a decision not to approve an application. These regulatory requirements may require us to amend our clinical trial protocols, conduct additional preclinical studies or clinical trials that may require regulatory or IRB approval, or otherwise cause delays in the approval or rejection of an application. Any delay in obtaining or failure to obtain required approvals could materially adversely affect our ability to generate revenue from the particular product candidate, which may materially harm our business, financial condition, results of operations, stock price and prospects.

If we experience delays in obtaining approval, if we fail to obtain approval of a product candidate or if the label for a product candidate does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate, the commercial prospects for such product candidate may be harmed and our ability to generate revenues from that product candidate may be materially impaired.

The FDA or a comparable foreign regulatory authority may determine that our product candidates have undesirable side effects that could delay or prevent their regulatory approval or commercialization.

To date, the most commonly reported adverse events observed for RP1 are local injection site reactions and systemic constitutional symptoms, such as fatigue, fevers and chills. However, there can be no assurance that additional undesirable side effects or serious adverse events will not be caused by or associated with RP1 or our other product candidates as they continue through or enter clinical development. Serious adverse events or undesirable side effects caused by our product candidates could cause us, IRBs, and other reviewing entities or regulatory authorities to interrupt, delay, or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. For example, if concerns are raised regarding the

safety of a new therapeutic as a result of undesirable side effects identified during clinical or preclinical testing, the FDA or comparable foreign regulatory authority may order us to cease further development, decline to approve the product candidate or issue a letter requesting additional data or information prior to making a final decision regarding whether or not to approve the product candidate. The FDA or comparable foreign regulatory authorities, or IRBs and other reviewing entities, may also require, or we may voluntarily develop, strategies for managing adverse events during clinical development, which could include restrictions on our enrollment criteria, the use of stopping criteria, adjustments to a study's design, or the monitoring of safety data by a data monitoring committee, among other strategies. The FDA or comparable foreign regulatory authority requests for additional data or information could also result in substantial delays in the approval of our product candidates.

Undesirable side effects caused by any of our product candidates could also result in denial of regulatory approval by the FDA or comparable foreign regulatory authorities for any or all targeted indications or the inclusion of unfavorable information in our product labeling, such as limitations on the indicated uses for which the products may be marketed or distributed, a label with significant safety warnings, including boxed warnings, contraindications, and precautions, a label without statements necessary or desirable for successful commercialization, or may result in requirements for costly postmarketing testing and surveillance, or other requirements, including REMS, to monitor the safety or efficacy of the products, and in turn prevent us from commercializing and generating revenues from the sale of our product candidates. Undesirable side effects may limit the potential market for any approved products or could result in the discontinuation of the sales and marketing of the product, or withdrawal of product approvals. Later discovered undesirable side effects may further result in the imposition of a REMS, label revisions, post approval study requirements, or other testing and surveillance.

If any of our product candidates is associated with serious adverse events or undesirable side effects or have properties that are unexpected, we may need to abandon development or limit development of that product candidate to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk/benefit perspective. The therapeutic-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may materially harm our business, financial condition, results of operations, stock price and prospects.

Changes in product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates are developed through preclinical studies to later stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. Such changes may also require additional testing, or notification to, or approval by the FDA or a comparable foreign regulatory authority. This could delay completion of clinical trials, require the conduct of bridging clinical trials or studies, require the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and/or jeopardize our ability to commence product sales and generate revenue.

Regulatory approval by the FDA or comparable foreign regulatory authorities is limited to those specific indications and conditions for which approval has been granted, and we may be subject to substantial fines, criminal penalties, injunctions, or other enforcement actions if we are determined to be promoting the use of our products for unapproved or "off label" uses, resulting in damage to our reputation and business.

We must comply with requirements concerning advertising and promotion for any product candidates for which we obtain marketing approval. Promotional communications with respect to therapeutics are subject to a variety of legal and regulatory restrictions and continuing review by the FDA, Department of Justice, Department of Health and Human Services' Office of Inspector General, state attorneys general, members of Congress, and the public. When the FDA or comparable foreign regulatory authorities issue regulatory approval for a product candidate, the regulatory approval is limited to those specific uses and indications for which a product is approved. If we are not able to obtain FDA approval for desired uses or indications for our product candidates, we may not market or promote them for those indications and uses, referred to as off label uses, and our business, financial condition, results of operations, stock price and prospects may be materially harmed. We also must sufficiently substantiate any claims that we make for our products, including claims comparing our products to other companies' products, and must abide by the FDA's strict requirements regarding the content of promotion and advertising.

While physicians may choose to prescribe products for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, we are prohibited from marketing and promoting the products for indications and uses that are not specifically approved by the FDA. These off label uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the United States generally do not restrict or regulate the behavior of physicians in their choice of treatment within the practice of medicine. Regulatory authorities do, however, restrict communications by biopharmaceutical companies concerning off label use.

If we are found to have impermissibly promoted any of our product candidates, we may become subject to significant liability and government fines. The FDA and other agencies actively enforce the laws and regulations regarding product promotion, particularly those prohibiting the promotion of off label uses, and a company that is found to have improperly promoted a product may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

In the United States, engaging in the impermissible promotion of our products, following approval, for off label uses can also subject us to false claims and other litigation under federal and state statutes. These include fraud and abuse and consumer protection laws, which can lead to civil and criminal penalties and fines and agreements with governmental authorities that materially restrict the manner in which we promote or distribute therapeutic products and conduct our business. These restrictions could include corporate integrity agreements, suspension or exclusion from participation in federal and state healthcare programs, and suspension and debarment from government contracts and refusal of orders under existing government contracts. These False Claims Act lawsuits against manufacturers of drugs and biologics have increased significantly in volume and breadth. In addition, False Claims Act lawsuits may expose manufacturers to follow-on claims by private payers based on fraudulent marketing practices. This growth in litigation has increased the risk that a biopharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, as well as criminal and civil penalties, agree to comply with burdensome reporting and compliance obligations, and be excluded from Medicare, Medicaid, or other federal and state healthcare programs. If we do not lawfully promote our approved products, if any, we may become subject to such litigation and, if we do

not successfully defend against such actions, those actions may have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

In the United States, the promotion of biopharmaceutical products is subject to additional FDA requirements and restrictions on promotional statements. If after one or more of our product candidates obtains marketing approval the FDA determines that our promotional activities violate its regulations and policies pertaining to product promotion, it could request that we modify our promotional materials or subject us to regulatory or other enforcement actions, including issuance of warning letters or untitled letters, suspension or withdrawal of an approved product from the market, requests for recalls, payment of civil fines, disgorgement of money, imposition of operating restrictions, injunctions or criminal prosecution, and other enforcement actions. Similarly, industry codes in foreign jurisdictions may prohibit companies from engaging in certain promotional activities and regulatory agencies in various countries may enforce violations of such codes with civil penalties. If we become subject to regulatory and enforcement actions our business, financial condition, results of operations, stock price and prospects will be materially harmed.

Even if our product candidates receive regulatory approval, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense and limit how we manufacture and market our products.

Any product candidate for which we obtain marketing approval will be subject to extensive and ongoing requirements of and review by the FDA and comparable foreign regulatory authorities, including requirements related to the manufacturing processes, post approval clinical data, labeling, packaging, distribution, adverse event reporting, shortage reporting, risk management plans, supply chain security, storage, recordkeeping, export, import, advertising, marketing, and promotional activities for such product. These requirements further include submissions of safety and other postmarketing information, including manufacturing deviations and reports, registration and listing requirements, the payment of annual fees, continued compliance with current Good Manufacturing Practice, or cGMP, requirements relating to manufacturing, quality control, quality assurance, and corresponding maintenance of records and documents, and good clinical practices, or GCPs, for any clinical trials that we conduct post approval.

The FDA and comparable foreign regulatory authorities will continue to closely monitor the safety profile of any product even after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of any of our product candidates, they may withdraw approval, issue public safety alerts, require labeling changes or establishment of a REMS or similar strategy, impose significant restrictions on a product's indicated uses or marketing, or impose ongoing requirements for potentially costly post approval studies or postmarket surveillance. Any such restrictions could limit sales of the product.

We and any of our suppliers or collaborators, including our contract manufacturers, could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMPs and other FDA regulatory requirements. Application holders must further notify the FDA, and depending on the nature of the change, obtain FDA preapproval for product and manufacturing changes.

In addition, later discovery of previously unknown adverse events or that the product is less effective than previously thought or other problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements both before and after approval, may yield various negative results, including:

- restrictions on manufacturing, distribution, or marketing of such products;

- restrictions on the labeling, including required additional warnings, such as black boxed warnings, contraindications, precautions, and restrictions on the approved indication or use;
- modifications to promotional pieces;
- issuance of corrective information;
- requirements to conduct postmarketing studies or other clinical trials;
- clinical holds or termination of clinical trials;
- requirements to establish or modify a REMS or similar strategy;
- changes to the way the product candidate is administered;
- liability for harm caused to patients or subjects;
- reputational harm;
- the product becoming less competitive;
- warning, untitled, or cyber letters;
- suspension of marketing or withdrawal of the products from the market;
- regulatory authority issuance of safety alerts, Dear Healthcare Provider letters, press releases, or other communications containing warnings or other safety information about the product candidate;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recalls of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure or detention;
- FDA debarment, suspension and debarment from government contracts, and refusal of orders under existing government contracts, exclusion from federal healthcare programs, consent decrees, or corporate integrity agreements; or
- injunctions or the imposition of civil or criminal penalties, including imprisonment.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, or could substantially increase the costs and expenses of commercializing such product, which in turn could delay or prevent us from generating significant revenues from its marketing and sale. Any of these events could further have other material and adverse effects on our operations and business and could adversely impact our business, financial condition, results of operations, stock price and prospects.

The FDA's policies or those of comparable foreign regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates, limit the marketability of our product candidates, or impose additional regulatory obligations on us. Changes in medical practice and standard of care may also impact the marketability of our product candidates.

If we are slow or unable to adapt to changes in existing requirements, standards of care, or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we

may lose any marketing approval that we may have obtained and be subject to regulatory enforcement action.

Should any of the above actions take place, we could be prevented from or significantly delayed in achieving profitability. Further, the cost of compliance with post approval regulations may have a negative effect on our operations and business and could adversely impact our business, financial condition, results of operations, stock price and prospects.

Obtaining and maintaining marketing approval for our product candidates in one jurisdiction would not mean that we will be successful in obtaining marketing approval of that product candidate in other jurisdictions, which could prevent us from marketing our products internationally.

Obtaining and maintaining marketing approval of our product candidates in one jurisdiction would not guarantee that we will be able to obtain or maintain marketing approval in any other jurisdiction, while a failure or delay in obtaining marketing approval in one jurisdiction may have a negative effect on the marketing approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable foreign regulatory authorities must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from and, in some cases, greater than, those in the United States, including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. Additionally, the outcome of the United Kingdom's impending withdrawal from the European Union, commonly referred to as Brexit, remains uncertain. Since a significant proportion of the regulatory framework in the United Kingdom is derived from European Union directives and regulations, the withdrawal of the United Kingdom from the European Union could materially impact the regulatory regime with respect to the approval of our product candidates in the United Kingdom or the European Union.

Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign marketing approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed. If we obtain approval for any product candidate and ultimately commercialize that product in foreign markets, we would be subject to additional risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements and the reduced protection of intellectual property rights in some foreign countries.

Risks related to commercialization

If we are unable to successfully commercialize any product candidate for which we receive regulatory approval, or experience significant delays in doing so, our business will be materially harmed.

If we are successful in obtaining marketing approval from applicable regulatory authorities for RP1 or any of our other product candidates, our ability to generate revenues from our product candidates will depend on our success in:

- launching commercial sales of our product candidates, whether alone or in collaboration with others;

- receiving an approved label with claims that are necessary or desirable for successful marketing, and that does not contain safety or other limitations that would impede our ability to market the product candidates;
- creating market demand for our product candidates through marketing, sales and promotion activities;
- hiring, training, and deploying a sales force or contracting with third parties to commercialize product candidates in the United States;
- manufacturing product candidates in sufficient quantities and at acceptable quality and cost to meet commercial demand at launch and thereafter;
- establishing and maintaining agreements with wholesalers, distributors, and group purchasing organizations on commercially reasonable terms;
- creating partnerships with, or offering licenses to, third parties to promote and sell product candidates in foreign markets where we receive marketing approval;
- maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- achieving market acceptance of our product candidates by patients, the medical community, and third-party payors;
- achieving appropriate reimbursement for our product candidates;
- effectively competing with other therapies; and
- maintaining a continued acceptable safety profile of our product candidates following launch.

To the extent we are not able to do any of the foregoing, our business, financial condition, results of operations, stock price and prospects will be materially harmed.

We face significant competition from other biopharmaceutical and biotechnology companies, academic institutions, government agencies, and other research organizations, which may result in others discovering, developing or commercializing products more quickly or marketing them more successfully than us. If their product candidates are shown to be safer or more effective than ours, our commercial opportunity may be reduced or eliminated.

The development and commercialization of cancer immunotherapy products is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary rights. We face competition with respect to our current product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major biopharmaceutical companies, specialty biopharmaceutical companies, and biotechnology companies worldwide. There are a number of large biopharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of solid tumors, including oncolytic immunotherapy and cancer vaccine approaches. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

While our product candidates are intended to be used in combination with other drugs with different mechanisms of action, if and when marketed they will still compete with a number of drugs that are currently marketed or in development that also target cancer. To compete effectively with these drugs, our product candidates will need to demonstrate advantages in clinical efficacy and safety compared to these competitors when used alone or in combination with other drugs.

Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are easier to administer or are less expensive alone or in combination with other therapies than any products that we may develop alone or in combination with other therapies. Our competitors also may obtain FDA or comparable foreign regulatory authority approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors coverage decisions.

Many of the companies with which we are competing or may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Mergers and acquisitions in the biopharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in developing or acquiring technologies complementary to, or necessary for, our programs. If we are unable to successfully compete with these companies our business, financial condition, results of operations, stock price and prospects may be materially harmed.

If we are unable to establish effective marketing, sales and distribution capabilities or enter into agreements with third parties to market and sell our product candidates, if they are approved, the revenues that we generate may be limited and we may never become profitable.

We currently do not have a commercial infrastructure for the marketing, sale, and distribution of our product candidates. If and when our product candidates receive marketing approval, we intend to commercialize our product candidates on our own in the United States and potentially with pharmaceutical or biotechnology partners in other geographies. In order to commercialize our products, we must build our marketing, sales, and distribution capabilities or make arrangements with third parties to perform these services. We may not be successful in doing so. Should we decide to move forward in developing our own marketing capabilities, we may incur expenses prior to product launch or even approval in order to recruit a sales force and develop a marketing and sales infrastructure. If a commercial launch is delayed as a result of FDA or comparable foreign regulatory authority requirements or other reasons, we would incur these expenses prior to being able to realize any revenue from sales of our product candidates. Even if we are able to effectively hire a sales force and develop a marketing and sales infrastructure, our sales force and marketing teams may not be successful in commercializing our product candidates. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

We may also or alternatively decide to collaborate with third-party marketing and sales organizations to commercialize any approved product candidates in the United States, in which event, our ability to generate product revenues may be limited. To the extent we rely on third parties to commercialize any products for which we obtain regulatory approval, we may receive less revenues than if we commercialized these products ourselves, which could materially harm our prospects. In addition, we would have less control over the sales efforts of any other third parties involved in our commercialization efforts, and could be held liable if they failed to comply with applicable legal or regulatory requirements.

We have no prior experience in the marketing, sale, and distribution of biopharmaceutical products, and there are significant risks involved in building and managing a commercial infrastructure. The establishment and development of commercial capabilities, including compliance plans, to market any products we may develop will be expensive and time consuming and could delay any product

launch, and we may not be able to successfully develop this capability. We will have to compete with other biopharmaceutical and biotechnology companies, including oncology-focused companies, to recruit, hire, train, manage, and retain marketing and sales personnel, which is expensive and time consuming and could delay any product launch. Developing our sales capabilities may also divert resources and management attention away from product development.

In the event we are unable to develop a marketing and sales infrastructure, we may not be able to commercialize our product candidates in the United States or elsewhere, which could limit our ability to generate product revenues and materially harm our business, financial condition, results of operations, stock price and prospects. Factors that may inhibit our efforts to commercialize our product candidates include:

- the inability to recruit, train, manage, and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe our product candidates;
- our inability to effectively oversee a geographically dispersed sales and marketing team;
- the costs associated with training sales and marketing personnel on legal and regulatory compliance matters and monitoring their actions;
- an inability to secure adequate coverage and reimbursement by government and private health plans;
- the clinical indications for which the products are approved and the claims that we may make for the products;
- limitations or warnings, including distribution or use restrictions, contained in the products' approved labeling;
- any distribution and use restrictions imposed by the FDA or comparable foreign regulatory authorities or to which we agree as part of a mandatory REMS or voluntary risk management plan;
- liability for sales or marketing personnel who fail to comply with the applicable legal and regulatory requirements;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization or engaging a contract sales organization.

Our product candidates are based on a novel approach to the treatment of cancer, which makes it difficult to predict the time and cost of product candidate development.

We have concentrated all of our research and development efforts on product candidates based on our Immulytic platform, and our future success depends on the successful development of this therapeutic approach. There can be no assurance that any development problems we experience in the future will not cause significant delays or unanticipated costs, or that such development problems can be solved. Should we encounter development problems, including unfavorable preclinical or clinical trial results, the FDA and foreign regulatory authorities may refuse to approve our product candidates, or may require additional information, tests, or trials, which could significantly delay product development and significantly increase our development costs. Moreover, even if we are able to provide the requested information or trials to the FDA, there would be no guarantee that the FDA would accept

them or approve our product candidates. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process, or developing or qualifying and validating product release assays, other testing and manufacturing methods, and our equipment and facilities in a timely manner, which may prevent us from completing our clinical trials or commercializing our product candidates on a timely or profitable basis, if at all.

In addition, the clinical trial requirements of the FDA and comparable foreign regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The FDA and comparable foreign regulatory authorities have limited experience with the approval of oncolytic immunotherapies. Only one oncolytic immunotherapy, T-Vec, has received FDA approval to date. Any product candidates that are approved may be subject to extensive post approval regulatory requirements, including requirements pertaining to manufacturing, distribution, and promotion. We may need to devote significant time and resources to compliance with these requirements.

If our product candidates do not achieve broad market acceptance, the revenues that we generate from their sales may be limited, and we may never become profitable.

We have never commercialized a product candidate for any indication. Even if our product candidates are approved by the appropriate regulatory authorities for marketing and sale, they may not gain acceptance among physicians, patients, third-party payors, and others in the medical community. If any product candidates for which we obtain regulatory approval do not gain an adequate level of market acceptance, we could be prevented from or significantly delayed in achieving profitability. Market acceptance of our product candidates by the medical community, patients, and third party payors will depend on a number of factors, some of which are beyond our control. For example, physicians are often reluctant to switch their patients and patients may be reluctant to switch from existing therapies even when new and potentially more effective or safer treatments enter the market.

Efforts to educate the medical community and third party payors on the benefits of our product candidates may require significant resources and may not be successful. If any of our product candidates is approved but does not achieve an adequate level of market acceptance, we could be prevented from or significantly delayed in achieving profitability. The degree of market acceptance of any of our product candidates will depend on a number of factors, including:

- the efficacy of our product candidates in combination with marketed checkpoint blockade drugs;
- the commercial success of the checkpoint blockade drugs with which our products are co-administered;
- the prevalence and severity of adverse events associated with our product candidates or those products with which they are co-administered;
- the clinical indications for which the products are approved and the approved claims that we may make for the products;
- limitations or warnings contained in the product's FDA-approved labeling or those of comparable foreign regulatory authorities, including potential limitations or warnings for our product candidates that may be more restrictive than other competitive products;
- changes in the standard of care for the targeted indications for our product candidates, which could reduce the marketing impact of any claims that we could make following FDA approval or approval by comparable foreign regulatory authorities, if obtained;

- the relative convenience and ease of administration of our product candidates by direct injection into tumors, a less common method for the administration of oncology therapies than systemic administration, which may result in slower adoption of our therapies;
- the relative convenience and ease of administration of any products with which our product candidates are co-administered;
- the cost of treatment compared with the economic and clinical benefit of alternative treatments or therapies;
- the availability of adequate coverage or reimbursement by third parties, such as insurance companies and other healthcare payors, and by government healthcare programs, including Medicare and Medicaid;
- the price concessions required by third-party payors to obtain coverage;
- the extent and strength of our marketing and distribution of our product candidates;
- the safety, efficacy, and other potential advantages over, and availability of, alternative treatments already used or that may later be approved;
- distribution and use restrictions imposed by the FDA or comparable foreign regulatory authorities with respect to our product candidates or to which we agree as part of a REMS or voluntary risk management plan;
- the timing of market introduction of our product candidates, as well as competitive products;
- our ability to offer our product candidates for sale at competitive prices;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the extent and strength of our third-party manufacturer and supplier support;
- the actions of companies that market any products with which our product candidates are co-administered;
- the approval of other new products;
- adverse publicity about our product candidates or any products with which they are co-administered, or favorable publicity about competitive products; and
- potential product liability claims.

The size of the potential market for our product candidates is difficult to estimate and, if any of our assumptions are inaccurate, the actual markets for our product candidates may be smaller than our estimates.

The potential market opportunities for our product candidates are difficult to estimate and will depend in large part on the drugs with which our product candidates are co-administered and the success of competing therapies and therapeutic approaches. In particular, the market opportunity for oncolytic immunotherapies is hard to estimate given that it is an emerging field with only one existing FDA-approved oncolytic immunotherapy, T-Vec, which has yet to enjoy broad market acceptance. Our estimates of the potential market opportunities are predicated on many assumptions, which may include industry knowledge and publications, third-party research reports, and other surveys. Although we believe that our internal assumptions are reasonable, these assumptions involve the exercise of significant judgment on the part of our management, are inherently uncertain, and their reasonableness has not been assessed by an independent source. If any of the assumptions proves to be inaccurate, the actual markets for our product candidates could be smaller than our estimates of the potential market opportunities.

Negative developments in the field of immuno-oncology could damage public perception of RP1 or any of our other product candidates and negatively affect our business.

The commercial success of our product candidates will depend in part on public acceptance of the use of cancer immunotherapies. Adverse events in clinical trials of RP1 or our other product candidates or in clinical trials of others developing similar products and the resulting publicity, as well as any other negative developments in the field of immuno-oncology that may occur in the future, including in connection with competitor therapies, could result in a decrease in demand for RP1 or our other product candidates that we may develop. These events could also result in the suspension, discontinuation, or clinical hold of or modification to our clinical trials. If public perception is influenced by claims that the use of cancer immunotherapies is unsafe, whether related to our therapies or those of our competitors, our product candidates may not be accepted by the general public or the medical community and potential clinical trial subjects may be discouraged from enrolling in our clinical trials. As a result, we may not be able to continue or may be delayed in conducting our development programs.

As our product candidates consist of a modified virus, adverse developments in antiviral vaccines or clinical trials of other oncolytic immunotherapy products based on viruses may result in a disproportionately negative effect for RP1 or our other product candidates as compared to other products in the field of immuno-oncology that are not based on viruses. Future negative developments in the field of immuno-oncology or the biopharmaceutical industry could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of our products. Any increased scrutiny could delay or increase the costs of obtaining marketing approval for RP1 or our other product candidates.

Risks related to our financial position and need for additional capital

We are a clinical stage biopharmaceutical company with a very limited operating history. We have incurred net losses since our inception and anticipate that we will continue to incur substantial and increasing net losses in the foreseeable future. We may never achieve or sustain profitability.

We are a clinical stage biopharmaceutical company with a limited operating history, and we are early in our development efforts. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain marketing approval and become commercially viable. We have financed our operations to date primarily through the sale of equity securities, including the sale of our common stock in our public offerings. Since our inception, most of our resources have been dedicated to the preclinical and clinical development of our Immulytic platform, RP1 and our other product candidates. The size of our future net losses will depend, in part, on our future expenses and our ability to generate revenue, if any.

We are not profitable and have incurred losses in each period since our inception. For the years ended March 31, 2020 and 2019, we reported a net loss of $52.6 million and $30.8 million, respectively. At March 31, 2020, we had an accumulated deficit of $112.3 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek marketing approvals for, RP1, our other product candidates and any additional product candidates we may develop.

Even if we succeed in receiving marketing approval for and commercialize RP1, we will continue to incur substantial research and development and other expenditures to develop and market additional potential products. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend,

in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We have never generated any revenue from product sales, and our ability to generate revenue from product sales and become profitable will depend significantly on our success in achieving a number of goals.

We have no products approved for commercial sale, have not generated any revenue from product sales, and do not anticipate generating any revenue from product sales until after we have received marketing approval for the commercial sale of a product candidate, if ever. Our ability to generate revenue and achieve profitability depends significantly on our success in achieving a number of goals, including:

- completing research regarding, and preclinical and clinical development of, RP1 and our other product candidates;
- obtaining marketing approvals for RP1 and our other product candidates for which we complete clinical trials;
- developing a sustainable and scalable manufacturing process for RP1 and our other product candidates, including establishing and maintaining commercially viable supply and manufacturing relationships with third parties;
- launching and commercializing RP1 and our other product candidates for which we obtain marketing approvals, either directly or with a collaborator or distributor;
- obtaining market acceptance of RP1 and our other product candidates as viable treatment options;
- addressing any competing technological and market developments;
- identifying, assessing, acquiring and developing new product candidates;
- negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter;
- obtaining, maintaining, protecting, and expanding our portfolio of intellectual property rights, including patents, trade secrets, and know-how; and
- attracting, hiring, and retaining qualified personnel.

Even if our product candidates or any future product candidates that we develop are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any such product candidate. Our expenses could increase beyond expectations if we are required by the FDA or comparable foreign regulatory authorities to change our manufacturing processes or assays, or to perform clinical, nonclinical, or other types of studies in addition to those that we currently anticipate.

If we are successful in obtaining regulatory approvals to market RP1 or our other product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain marketing approval, the accepted price for the product, the ability to get reimbursement at any price, and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, the labels for our product candidates contain significant safety warnings, regulatory authorities impose burdensome or restrictive distribution requirements, or the reasonably accepted patient population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. If we are not able to generate revenue from the sale of any approved products, we could be prevented from or significantly delayed in achieving profitability.

We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development or commercialization efforts.

Our operations have consumed substantial amounts of cash since inception. At March 31, 2020, our cash and cash equivalents and short-term investments were $168.6 million We expect to continue to spend substantial amounts to continue the clinical and preclinical development of RP1 and our other product candidates. Accordingly, we will need to obtain substantial additional funds to achieve our business objectives. If we are able to gain marketing approval of any product candidate, we will require significant additional amounts of cash in order to launch and commercialize such product. In addition, other unanticipated costs may arise.

Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of researching and developing RP1 and our other product candidates, and conducting preclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining marketing approvals for RP1 and our other product candidates if clinical trials are successful;
- the success of any collaborations;
- the cost of commercialization activities for any approved product, including marketing, sales and distribution costs;
- the cost and timing of operating our manufacturing facility;
- the cost of manufacturing RP1 and our other product candidates for clinical trials in preparation for marketing approval and commercialization;
- our ability to establish and maintain strategic licensing or other arrangements and the financial terms of such agreements;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the timing, receipt, and amount of sales of, or royalties on, our future products, if any; and
- the emergence of competing cancer therapies and other adverse market developments.

We do not have any committed external source of funds or other support for our development efforts. Until we can generate sufficient product revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. Our ability to obtain debt financing may be limited by covenants we have made under our Loan and Security Agreement with Hercules Capital, Inc., or Hercules, and our pledge to Hercules of our assets as collateral. Based on our research and development plans, we expect that our existing cash and cash equivalents and short-term investments will enable us to fund our planned operating expenses and capital expenditure requirements through 2022. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. In addition, because the design and outcome of our planned and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of RP1 or our other product candidates.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

To the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, our existing stockholders' interest will be diluted. Debt financing, if available, would increase our fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we are unable to raise additional funds through equity or debt financings when needed, we may be required to grant rights to develop and market one or more of our product candidates or technologies that we would otherwise prefer to develop and market ourselves.

Risks related to intellectual property

If we are unable to obtain, maintain and protect our intellectual property rights for our technology and product candidates, or if our intellectual property rights are inadequate, our competitive position could be harmed.

Our commercial success will depend in part on our ability to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our technology, Immulytic platform, RP1 and our other product candidates. We rely on trade secret, patent, copyright and trademark laws, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection. We seek to protect our proprietary position by filing and prosecuting patent applications in the United States and abroad related to our technology and product candidates.

The patent positions of biotechnology and pharmaceutical companies generally are highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our licensed patents and any patents we own in the future are highly uncertain. The steps we have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights, both inside and outside of the United States.

Further, the examination process may require us to narrow the claims for our pending patent applications, which may limit the scope of patent protection that may be obtained if these applications issue. The scope of a patent may also be reinterpreted after issuance. The rights that may be granted under our future issued patents may not provide us with the proprietary protection or competitive advantages we are seeking. If we are unable to obtain and maintain patent protection for our technology or for RP1 or our other product candidates, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize products similar or superior to ours, and our ability to successfully commercialize RP1 or our other product candidates and future technologies may be adversely affected. It is also possible that we will fail to identify patentable aspects of inventions made in the course of our development and commercialization activities before it is too late to obtain patent protection on them.

In addition, the patent prosecution process is expensive, time consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. Although we enter into nondisclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, collaborators, and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. It is also possible that we will fail to identify patentable aspects of our research and development efforts in time to obtain patent protection.

For the core technology in our Immulytic platform and each of our product candidates, we have filed six patent applications under the PCT. Five of these PCT applications have entered the national phase and are pending in a range of countries, and one is still in the international phase. Three US patents have been granted. Other than the foregoing, none of our PCT-derived patent applications or U.S. provisional applications have been granted by a patent office and examination has started only in connection with the European and US national phase applications. Any future provisional patent applications are not eligible to become issued patents until, among other things, we file a non-provisional patent application within 12 months of filing of one or more of our related provisional patent applications. If we do not timely file any non-provisional patent applications, we may lose our priority date with respect to our provisional patent applications and any patent protection on the inventions disclosed in our provisional patent applications. Although we intend to timely file non-provisional patent applications relating to our provisional patent applications, we cannot predict whether any of our future patent applications will result in the issuance of patents that effectively protect our technology or RP1 or our other product candidates, or if any of our future issued patents will effectively prevent others from commercializing competitive products. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or in some cases not at all until they are issued as a patent. Therefore, we cannot be certain that we were the first to make the inventions claimed in our pending patent applications, or that we were the first to file for patent protection of such inventions.

Our pending applications cannot be enforced against third parties practicing the inventions claimed in such applications unless and until a patent issues from such applications. Because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, issued patents that we license from third parties or own in the future may be challenged in the courts or patent offices in the United States and abroad, including through opposition proceedings, derivation proceedings, *inter partes* review, interference proceedings or litigation. Such proceedings may result in the loss of patent protection, the narrowing of claims in such patents or the invalidity or unenforceability of such patents, which could limit our ability to stop others from using or commercializing similar or identical products, or limit the duration of the patent protection for our technology. Protecting against the unauthorized use of our patented inventions, trademarks and other intellectual property rights is expensive, time consuming, difficult and in some cases may not be possible. In some cases, it may be difficult or impossible to detect third party infringement or misappropriation of our intellectual property rights, even in relation to issued patent claims, and proving any such infringement may be even more difficult. If we are unable to obtain, maintain, and protect our intellectual property our competitive advantage could be harmed, and it could result in a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

In addition to seeking patent protection, we also rely on other proprietary rights, including protection of trade secrets, know-how and confidential and proprietary information. To maintain the confidentiality of our trade secrets and proprietary information, we enter into confidentiality agreements with our employees, consultants, collaborators and other third parties who have access to our trade secrets. Our agreements with employees also provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. In addition, in the event of unauthorized use or disclosure

of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. To the extent that our employees, consultants or contractors use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions.

Adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential information including a breach of our confidentiality agreements. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time consuming, and the outcome is unpredictable. In addition, some courts in and outside of the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. The disclosure of our trade secrets or the independent development of our trade secrets by a competitor or other third party would impair our competitive position and may materially harm our business, financial condition, results of operations, stock price and prospects.

Third parties may in the future initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could harm our business.

Our commercial success depends on our ability and the ability of our current or future collaborators to develop, manufacture, market and sell RP1 and our other product candidates, and to use our related proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. We may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our current and any other future product candidates, including interference proceedings, post-grant review, *inter partes* review and derivation proceedings before the U.S. Patent and Trademark Office, or USPTO. Third parties may assert infringement or other intellectual property claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third party's intellectual property rights, and we are unsuccessful in demonstrating that such intellectual property rights are invalid or unenforceable, we could be required to obtain a license from such third-party to continue developing, manufacturing and commercializing RP1 and our other product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be nonexclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We also could be forced, including by court order, to cease developing, manufacturing, and commercializing RP1 or our other product candidates. In addition, in any such proceeding or litigation, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, stock price and prospects. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar material adverse effect on our business.

In addition, we are developing certain of our product candidates in combination with nivolumab and cemiplimab, which are covered by patents or licenses held by BMS and Regeneron, respectively, to which we do not have a license other than for use in connection with the applicable clinical trial. We also plan to develop our product candidates in combination with products developed by additional companies that are covered by patents or licenses held by those entities to which we do not have a license. In the event that a labeling instruction is required in product packaging recommending that combination, we could be accused of, or held liable for, infringement of the third-party patents covering the product candidate or product recommended for administration with RP1 or our other product

candidates. In such a case, we could be required to obtain a license from the other company or institution to use the required or desired package labeling, which may not be available on commercially reasonable terms, or at all.

We may not be able to protect our intellectual property and proprietary rights throughout the world.

Filing, prosecuting and defending patents on our technology in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws and practices of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop and/or manufacture their own products and may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as that in the United States. These products may compete with our products and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the granting or enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to obtain patent rights or stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally in those countries. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to protect and enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property we develop or license.

In addition, the laws of certain foreign countries may not protect our rights to the same extent as the laws of the United States, and those foreign laws may also be subject to change. For example, methods of treatment and manufacturing processes may not be patentable in certain jurisdictions, and the requirements for patentability may differ in certain countries. Furthermore, biosimilar product manufacturers or other competitors may challenge the scope, validity and enforceability of our patents, requiring us to engage in complex, lengthy and costly litigation or proceedings.

Moreover, many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. Many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired and our business and results of operations may be adversely affected.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payments and other similar provisions during the patent application

process and to maintain patents after they are issued. For example, periodic maintenance fees, renewal fees, annuity fees and various other government fees on issued patents and patent applications often must be paid to the USPTO and foreign patent agencies over the lifetime of our licensed patents or any patents we own in the future. In certain circumstances, we may rely on future licensing partners to take the necessary action to comply with these requirements with respect to licensed intellectual property. Although an unintentional lapse can be cured for a period of time by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, nonpayment of fees and failure to properly legalize and submit formal documents. If we fail to obtain and maintain the patents and patent applications covering our products or procedures, we may not be able to stop a competitor from marketing products that are the same as or similar to RP1 or our other product candidates, which could have a material adverse effect on our business.

Changes to the patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect RP1 and our other product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs. Patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act, or the Leahy-Smith Act, signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings, even in applications filed before the Leahy-Smith Act came into effect. Because these third party challenges before the USPTO have a lower evidentiary bar for patent invalidation as compared with the evidentiary standard in a U.S. Federal Court, it is possible for a third party to invalidate a patent claim before the USPTO that would not have been invalidated before a District Court. Additionally, rights of review and appeal for these USPTO third party challenges is still a developing area of law.

On March 16, 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. Since patent applications in the United States and many other countries are confidential for a period of time after a filing, we cannot be certain that we were the first to file any patent application or first to invent any of the inventions claimed in our patents or patent applications. Thus, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO

and the relevant lawmaking bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming and unsuccessful and have a material adverse effect on the success of our business.

Competitors may infringe any future licensed patents or any patent we own in the future or misappropriate or otherwise violate our intellectual property rights. We may also be required to defend against claims of infringement and our licensed patents and any patents we own in the future may become involved in priority or other intellectual property related disputes. To counter infringement or unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. Also, third parties may initiate legal proceedings against us to assert that we are infringing their intellectual property rights or to challenge the validity or scope of our owned or licensed intellectual property rights. These proceedings can be expensive and time consuming. Many of our current and potential competitors have the ability to dedicate substantially greater resources to conduct intellectual property related litigations or proceedings than we can. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. Litigation and other intellectual property related proceedings could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, in an infringement proceeding, a court may decide that a patent owned by or licensed to us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or other intellectual property related proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation in the United States, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments in any such proceedings. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Any of the foregoing may have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

We may be subject to claims by third parties asserting that our collaborators, employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees, including our senior management team, were previously employed at, or consulted for, universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Our collaborators' employees may currently be or previously have been employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these persons, including each member of our senior management team, executed proprietary rights, nondisclosure and noncompetition agreements, or similar agreements, in connection with such previous employment or consulting agreements, that assigned ownership of intellectual property relating to work performed under such agreements to the contracting third party. Although we take steps to ensure that our employees do not use, claim as theirs, or misappropriate the intellectual property, proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used, claimed as theirs,

misappropriated or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third-party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms, or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management. Any of the foregoing may have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed confidential information of third parties or are in breach of noncompetition or nonsolicitation agreements with our competitors.

We could be subject to claims that we or our employees, including senior management, have inadvertently or otherwise used or disclosed alleged trade secrets or other confidential information of former employers or competitors or others. Although we take steps to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we caused an employee to breach the terms of their noncompetition or nonsolicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor or other party. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to RP1 and our other product candidates, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers, competitors or other parties. An inability to incorporate such technologies or features would have a material adverse effect on our business, and may prevent us from successfully commercializing RP1 and our other product candidates. In addition, we may lose valuable intellectual property rights or personnel as a result of such claims. Moreover, any such litigation or the threat thereof may adversely affect our ability to hire employees or consultants. A loss of key personnel or their work product could hamper or prevent our ability to develop and commercialize RP1 and our other product candidates, which could have an adverse effect on our business, financial condition, results of operations, stock price and prospects.

If we obtain any issued patents covering our technology, such patents could be found invalid or unenforceable if challenged in court or before the USPTO or comparable foreign regulatory authority.

If we or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering any of our technology, the defendant could counterclaim that the patent covering our product candidate is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Grounds for a validity challenge could be, among other things, an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be, among other things, an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include reexamination, *inter partes* review, post-grant review, interference proceedings, derivation proceedings

and equivalent proceedings in foreign jurisdictions, such as opposition proceedings. Such proceedings could result in revocation, cancellation or amendment of our patents in such a way that they no longer cover and protect RP1 and our other product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. For example, with respect to the validity of our licensed patents or any patents we obtain in the future, we cannot be certain that there is no invalidating prior art of which we, our or our licensing partners' patent counsel, and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on RP1 and our other product candidates. Such a loss of patent protection could have a material adverse impact on our business.

Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time, and our product candidates for which we intend to seek approval as biological products may face competition sooner than anticipated.

Given the amount of time required for the development, testing and regulatory review of new product candidates, such as RP1 and our other product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, but no longer than 14 years from the product's approval date, which is limited to the approved indication (or any additional indications approved during the period of extension). However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authorities in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their products earlier than might otherwise be the case, which could have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

The enactment of the Biologics Price Competition and Innovation Act of 2009, or BPCIA, as part of the Patient Protection and Affordable Care Act, or ACA, created an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an existing brand product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product was approved under a BLA. Certain changes, however, and supplements to an approved BLA, and subsequent applications filed by the same sponsor, manufacturer, licensor, predecessor in interest, or other related entity do not qualify for the 12-year exclusivity period.

RP1 and our other product candidates are all biological product candidates. We anticipate being awarded market exclusivity for each of our biological product candidates that is subject to its own BLA for 12 years in the United States, 10 years in Europe and significant durations in other markets. However, the term of the patents that cover such product candidates may not extend beyond the applicable market exclusivity awarded by a particular country. For example, in the United States, a third party could submit a marketing application for a biosimilar product four years after approval of our biological product, the FDA could immediately review the application and approve the biosimilar product for marketing 12 years after approval of our biological product, and if all of the patents that cover our particular biological product expire before the 12 year market exclusivity expires, the biosimilar sponsor could then immediately begin marketing. Alternatively, a third party could submit a full BLA for a similar or identical product any time after approval of our biological product, and the FDA could immediately review and approve the similar or identical product for marketing and the

third party could begin marketing the similar or identical product upon expiry of all of the patents that cover our particular biological product.

There is also a risk that this exclusivity could be changed in the future. For example, this exclusivity could be shortened due to congressional action or through other actions, including future proposed budgets, international trade agreements and other arrangements or proposals. Additionally, there is a risk that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. The extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. It is also possible that payers will give reimbursement preference to biosimilars over reference biologics, even absent a determination of interchangeability.

To the extent that we do not receive any anticipated periods of regulatory exclusivity for our product candidates or the FDA or foreign regulatory authorities approve any biosimilar, interchangeable, or other competing products to our product candidates, it could have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

Risks related to manufacturing and our reliance on third parties

We have agreements with BMS and Regeneron, and in the future may have agreements with other companies, to obtain the supply of anti-PD-1 therapies for the development of our product candidates. If our relationships with BMS, Regeneron, or any future collaborator or supplier are not successful, we may be delayed in completing the development of our product candidates.

We have entered into arrangements with BMS and Regeneron as part of our clinical development for RP1 and RP2. BMS is providing nivolumab, its anti-PD-1 therapy, for use in our ongoing Phase 1/2 clinical trials with RP1 and RP2 and Regeneron is providing cemiplimab, its anti-PD-1 therapy, for use in our randomized, controlled Phase 2 clinical trial with RP1 in approximately 240 patients with CSCC and may potentially do so for other clinical trials in the future. We may also enter into agreements with additional companies for the supply of anti-PD-1 therapies for use in the development of RP1 and our other product candidates. The outcome of these clinical trials is dependent both on the performance of our partners' products and product candidates and also on our partners' ability to deliver sufficient quantities of adequately produced product. Should any of our partners' products or product candidates fail to produce the results that we anticipate, we may have to re-run clinical trials for RP1 or our other product candidates or may otherwise be delayed in the commercialization of RP1 or our other product candidates. Similarly, should any partner fail to provide us with a product or product candidate that suits our requirements, we may have to re-run clinical trials for RP1 or our other product candidates or may be otherwise delayed in the commercialization of RP1 or our other product candidates.

Our collaboration agreements with any future partners may not be successful, which could adversely affect our ability to develop and commercialize our product candidates.

We may in the future seek collaboration arrangements with other parties for the development or commercialization of our product candidates. The success of any collaboration arrangements may depend on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these arrangements. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority.

Collaborations with biopharmaceutical companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration could adversely affect us financially and could harm our business reputation.

Any future collaborations we might enter into may pose a number of risks, including the following:

- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could fail to make timely regulatory submissions for a product candidate;
- collaborators may not comply with all applicable regulatory requirements or may fail to report safety data in accordance with all applicable regulatory requirements, which could subject them or us to regulatory enforcement actions;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product candidate or product;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation; and
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability.

If any collaborations we might enter into in the future do not result in the successful development and commercialization of products or if one of our collaborators subsequently terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under such potential future collaboration. If we do not receive the funding we expect under the agreements, our development of our product candidates could be delayed and we may need additional resources to develop our product candidates and our product platform.

Additionally, if any future collaborator of ours is involved in a business combination, the collaborator might deemphasize or terminate development or commercialization of any product candidate it licenses to us. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our reputation in the business and financial communities could be adversely affected.

We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for any collaboration will depend upon, among other things, our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors.

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms, or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our product platform and our business may be materially and adversely affected.

We rely, and expect to continue to rely, on third parties to conduct, supervise, and monitor our preclinical studies and clinical trials. If those third parties do not perform satisfactorily, including failing to meet deadlines for the completion of such trials or failing to comply with regulatory requirements, we may be unable to obtain regulatory approval for our product candidates or any other product candidates that we may develop in the future.

We rely on third-party CROs, study sites, and others to conduct, supervise, and monitor our preclinical studies and clinical trials for our product candidates and do not currently plan to independently conduct preclinical studies or clinical trials of any other potential product candidates. We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions, and clinical investigators, to conduct our preclinical studies and clinical trials. Although we have agreements governing their activities, we have limited influence over their actual performance and control only certain aspects of their activities. The failure of these third parties to successfully carry out their contractual duties or meet expected deadlines could substantially harm our business because we may be delayed in completing or unable to complete the studies required to support future approval of our product candidates, or we may not obtain marketing approval for or commercialize our product candidates in a timely manner or at all. Moreover, these agreements might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements our product development activities would be delayed and our business, financial condition, results of operations, stock price and prospects may be materially harmed.

Our reliance on these third parties for development activities will reduce our control over these activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards and our reliance on third parties does not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our trials is conducted in accordance with the general investigational plan and protocols for the trial. We must also ensure that our preclinical trials are conducted in accordance with the FDA's Good Laboratory Practice, or GLP, regulations, as appropriate. Moreover, the FDA and comparable foreign regulatory authorities require us to comply with standards, commonly referred to as GCPs for conducting, recording, and reporting the results of clinical trials to

assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections of trial sponsors, clinical investigators, and trial sites. If we or any of our third parties fail to comply with applicable GCPs or other regulatory requirements, we or they may be subject to enforcement or other legal actions, the data generated in our trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional studies.

In addition, we will be required to report certain financial interests of our third-party investigators if these relationships exceed certain financial thresholds or meet other criteria. The FDA or comparable foreign regulatory authorities may question the integrity of the data from those clinical trials conducted by investigators who may have conflicts of interest.

We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our trials complies with the applicable regulatory requirements. In addition, our clinical trials must be conducted with product candidates that were produced under cGMP regulations. Failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We also are required to register certain clinical trials and post the results of certain completed clinical trials on a government sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in enforcement actions and adverse publicity.

The third parties with which we work may also have relationships with other entities, some of which may be our competitors, for whom they may also be conducting trials or other therapeutic development activities that could harm our competitive position. In addition, such third parties are not our employees, and except for remedies available to us under our agreements with such third parties we cannot control whether or not they devote sufficient time and resources to our ongoing clinical, nonclinical, and preclinical programs. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our preclinical studies or clinical trials in accordance with regulatory requirements or our stated protocols, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements or for other reasons, our trials may be repeated, extended, delayed, or terminated; we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates; we may not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates, or we or they may be subject to regulatory enforcement actions. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed. To the extent we are unable to successfully identify and manage the performance of third-party service providers in the future, our business, financial condition, results of operations, stock price and prospects may be materially harmed.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative providers or to do so on commercially reasonable terms. Switching or adding additional third parties involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines.

We also rely on other third parties to store and distribute our products for the clinical trials that we conduct. Any performance failure on the part of our distributors could delay clinical development, marketing approval, or commercialization of our product candidates, which could result in additional losses and deprive us of potential product revenue.

If the manufacturers upon which we rely fail to produce our product candidates in the volumes that we require on a timely basis, or fail to comply with stringent regulations applicable to biopharmaceutical manufacturers, we may face delays in the development and commercialization of, or be unable to meet demand for, our product candidates and may lose potential revenues.

Until our manufacturing facility is fully operational and for a period of time thereafter, we will rely on third-party contract manufacturers to manufacture our clinical trial product supplies. There can be no assurance that our clinical development will not be limited, interrupted, or of satisfactory quality or continue to be available at acceptable prices. In particular, any replacement of our contract manufacturer could require significant effort and expertise because there may be a limited number of qualified replacements. Any delays in obtaining adequate supplies of our product candidates that meet the necessary quality standards may delay our development or commercialization.

We may not succeed in our efforts to establish manufacturing relationships or other alternative arrangements for any of our product candidates or programs. Our product candidates may compete with other products and product candidates for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that are both capable of manufacturing and filling our viral product for us and willing to do so. If our existing third-party manufacturers, or the third parties that we engage in the future, should cease to work with us, we likely would experience delays in obtaining sufficient quantities of our product candidates for us to meet commercial demand or to advance our clinical trials while we identify and qualify replacement suppliers. If for any reason we are unable to obtain adequate supplies of our product candidates or the therapeutic substances used to manufacture them, it will be more difficult for us to develop our product candidates and compete effectively. Further, even if we do establish such collaborations or arrangements, our third-party manufacturers may breach, terminate, or not renew these agreements.

Any problems or delays we experience in preparing for commercial scale manufacturing of a product candidate or component may result in a delay in product development timelines and FDA or comparable foreign regulatory authority approval of the product candidate or may impair our ability to manufacture commercial quantities or such quantities at an acceptable cost and quality, which could result in the delay, prevention, or impairment of clinical development and commercialization of our product candidates and may materially harm our business, financial condition, results of operations, stock price and prospects.

We currently have only one contract manufacturer for our product candidates for use in our clinical trials. In addition, we do not have any long-term commitments from our suppliers of clinical trial material or guaranteed prices for our product candidates or their components. The manufacture of biopharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of therapeutics often encounter difficulties in production, particularly in scaling up initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, shortages of qualified personnel or key raw materials, and compliance with strictly enforced federal, state, and foreign regulations. Our contract manufacturers may not perform as agreed. If our manufacturers were to encounter these or other difficulties, our ability to provide product candidates to patients in our clinical trials could be jeopardized.

Contract manufacturers of our product candidates may be unable to comply with our specifications, applicable cGMP requirements or other FDA, state or foreign regulatory requirements. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of a product candidate that may not be detectable in final product testing. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the

FDA or other regulatory authorities, they will not be able to secure or maintain regulatory approval for their manufacturing facilities. Any such deviations may also require remedial measures that may be costly and/or time consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business. Any delays in obtaining products or product candidates that comply with the applicable regulatory requirements may result in delays to clinical trials, product approvals, and commercialization. It may also require that we conduct additional studies.

While we are ultimately responsible for the manufacturing of our product candidates and therapeutic substances, other than through our contractual arrangements, we have little control over our manufacturers' compliance with these regulations and standards. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Any new manufacturers would need to either obtain or develop the necessary manufacturing know-how, and obtain the necessary equipment and materials, which may take substantial time and investment. We must also receive FDA approval for the use of any new manufacturers for commercial supply.

A failure to comply with the applicable regulatory requirements, including periodic regulatory inspections, may result in regulatory enforcement actions against our manufacturers or us (including fines and civil and criminal penalties, including imprisonment) suspension or restrictions of production, injunctions, delay or denial of product approval or supplements to approved products, clinical holds or termination of clinical trials, warning or untitled letters, regulatory authority communications warning the public about safety issues with the product candidate, refusal to permit the import or export of the products, product seizure, detention, or recall, operating restrictions, suits under the civil False Claims Act, corporate integrity agreements, consent decrees, withdrawal of product approval, environmental or safety incidents and other liabilities. If the safety of any quantities supplied is compromised due to our manufacturers' failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our product candidates.

Any failure or refusal to supply our product candidates or components for our product candidates that we may develop could delay, prevent or impair our clinical development or commercialization efforts. Any change in our manufacturers could be costly because the commercial terms of any new arrangement could be less favorable and because the expenses relating to the transfer of necessary technology and processes could be significant.

The transition of our manufacturing operations to our new facility may result in further delays or expenses, and we may not experience the anticipated operating efficiencies.

We have completed the build-out of, obtained an occupancy certificate with respect to, and successfully completed our first two tech transfers at, our approximately 63,000 square foot manufacturing facility in Framingham, Massachusetts at which we intend to operate our own manufacturing facility in order to secure supplies for pivotal studies and commercial launch. This facility is intended to give us control over key aspects of the supply chain for our products and product candidates. We may not experience the anticipated operating efficiencies as we commence manufacturing operations at the new facility. Any such delays may disrupt or delay the supply of our product candidates if we have not maintained a sufficient backup supply of our product candidates through third-party manufacturers. Moreover, changing manufacturing facilities may also require that we conduct additional studies, make notifications to the regulatory authorities, make additional filings to the regulatory authorities, and obtain regulatory authority approval for the new facilities, which may be delayed or which we may never receive. We will further need to comply with the FDA's and

applicable foreign regulatory authorities' cGMP requirements for the production of our product candidates for clinical trials and, if approved, commercial supply, and will be subject to FDA and comparable foreign regulatory authority inspection. These requirements include the qualification and validation of our manufacturing equipment and processes. We may not be able to develop or acquire the internal expertise and resources necessary for compliance with these requirements. If we fail to achieve the operating efficiencies that we anticipate, our manufacturing and operating costs may be greater than expected, which could have a material adverse impact on our operating results.

In operating our own manufacturing facility, we may be forced to devote greater resources and management time than anticipated, particularly in areas relating to operations, quality, regulatory, facilities and information technology. If we experience unanticipated employee turnover in any of these areas, we may not be able to effectively manage our ongoing manufacturing operations and we may not achieve the operating efficiencies that we anticipate from the new facility, which may negatively affect our product development timeline.

Any such problems could result in the delay, prevention, or impairment of clinical development and commercialization of our product candidates and may materially harm our business, financial condition, results of operations, stock price and prospects.

Risks related to legal and compliance matters

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability and have to limit the commercialization of any approved products and/or our product candidates.

The use of our product candidates in clinical trials, and the sale of any product for which we obtain regulatory approval, exposes us to the risk of product liability claims. We face inherent risk of product liability related to the testing of our product candidates in human clinical trials, including liability relating to the actions and negligence of our investigators, and will face an even greater risk if we commercially sell any product candidates that we may develop. For example, we may be sued if any product candidate we develop allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. Product liability claims might be brought against us by consumers, healthcare providers or others using, administering or selling our products. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of merit or eventual outcome, liability claims may result in:

- loss of revenue from decreased demand for our products and/or product candidates;
- impairment of our business reputation or financial stability;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- diversion of management attention;
- withdrawal of clinical trial participants and potential termination of clinical trial sites or entire clinical programs;
- the inability to commercialize our product candidates;
- significant negative media attention;

- decreases in our stock price;
- initiation of investigations and enforcement actions by regulators; and
- product recalls, withdrawals or labeling, marketing or promotional restrictions, including withdrawal of marketing approval.

We believe we have sufficient insurance coverage in place for our business operations. However, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We intend to expand our insurance coverage to include the sale of commercial products if we obtain FDA or comparable foreign regulatory approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing, or at all. Failure to obtain and retain sufficient product liability insurance at an acceptable cost could prevent or inhibit the commercialization of products we develop. On occasion, large judgments have been awarded in class action lawsuits based on therapeutics that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash, and materially harm our business, financial condition, results of operations, stock price and prospects.

We are subject to the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act and other anticorruption laws, as well as import and export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures, and legal expenses, which could adversely affect our business, financial condition, results of operations, stock price and prospects.

Our operations are subject to anticorruption laws, including the U.S. Foreign Corrupt Practices Act, or FCPA, the U.K. Bribery Act 2010, or the Bribery Act, and other anticorruption laws that apply in countries where we do business. The FCPA, the Bribery Act, and these other laws generally prohibit us and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. We also may participate in collaborations and relationships with third parties whose actions, if noncompliant, could potentially subject us to liability under the FCPA, Bribery Act or local anticorruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United States and the United Kingdom and authorities in the European Union, including applicable import and export control regulations, economic sanctions on countries and persons, anti-money laundering laws, customs requirements and currency exchange regulations, collectively referred to as the trade control laws.

We can provide no assurance that we will be completely effective in ensuring our compliance with all applicable anticorruption laws or other legal requirements, including trade control laws. If we are not in compliance with applicable anticorruption laws or trade control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations, stock price and prospects. Likewise, any investigation of any potential violations of these anticorruption laws or trade control laws by U.S., U.K. or other authorities could also have an adverse impact on our reputation, our business, financial condition, results of operations, stock price and prospects.

If we fail to comply with federal and state healthcare laws, including fraud and abuse and health and other information privacy and security laws, we could face substantial penalties and our business, financial condition, results of operations, stock price and prospects will be materially harmed.

We are subject to many federal and state healthcare laws, such as the federal Anti-Kickback Statute, the federal civil and criminal False Claims Acts, the civil monetary penalties statute, the Medicaid Drug Rebate statute and other price reporting requirements, the Veterans Health Care Act of 1992, or VHCA, the federal Health Insurance Portability and Accountability Act of 1996 (as amended by the Health Information Technology for Economics and Clinical Health Act, or HITECH), or HIPAA, the FCPA, the ACA, and similar state laws. Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws, and regulations pertaining to fraud and abuse, reimbursement programs, government procurement, and patients' rights are and will be applicable to our business. We would be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states and foreign jurisdictions in which we conduct our business. In the European Union, the data privacy laws are generally stricter than those that apply in the United States and include specific requirements for the collection of personal data of European Union persons or the transfer of personal data outside of the European Union to the United States to ensure that European Union standards of data privacy will be applied to such data.

If we or our operations are found to be in violation of any federal or state healthcare law, or any other governmental laws or regulations that apply to us, we may be subject to penalties, including civil, criminal, and administrative penalties, damages, fines, disgorgement, suspension and debarment from government contracts, and refusal of orders under existing government contracts, exclusion from participation in U.S. federal or state health care programs, corporate integrity agreements, and the curtailment or restructuring of our operations, any of which could materially adversely affect our ability to operate our business and our financial results. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, it may be subject to criminal, civil or administrative sanctions, including but not limited to, exclusions from participation in government healthcare programs, which could also materially affect our business.

Although an effective compliance program can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Moreover, achieving and sustaining compliance with applicable federal, state and foreign privacy, data protection, security, reimbursement, and fraud laws may prove costly. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

If the government or third-party payors fail to provide adequate coverage, reimbursement and payment rates for our product candidates, or if health maintenance organizations or long-term care facilities choose to use therapies that are less expensive or considered a better value, our revenue and prospects for profitability will be limited.

In both domestic and foreign markets, sales of our products will depend in part upon the availability of coverage and reimbursement from third-party payors. Such third-party payors include government health programs such as Medicare and Medicaid, managed care providers, private health insurers, and other organizations. Coverage decisions may depend upon clinical and economic standards that disfavor new therapeutic products when more established or lower cost therapeutic alternatives are already available or subsequently become available, even if our products are alone in a class. If reimbursement is not available, or is available only to limited levels, our product candidates may be competitively disadvantaged, and we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain a market share sufficient to realize a sufficient return on our or

their investments. Alternatively, securing favorable reimbursement terms may require us to compromise pricing and prevent us from realizing an adequate margin over cost.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved therapeutics. Marketing approvals, pricing, and reimbursement for new therapeutic products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a therapeutic before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription biopharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay commercial launch of the product, possibly for lengthy time periods, which may negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval. Our ability to commercialize our product candidates will depend in part on the extent to which coverage and reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Regulatory authorities and third-party payors, such as private health insurers, and health maintenance organizations, decide which medications they will cover and establish reimbursement levels. The healthcare industry is acutely focused on cost containment, both in the United States and elsewhere. Several third-party payors are requiring that companies provide them with predetermined discounts from list prices, are using preferred drug lists to leverage greater discounts in competitive classes, are disregarding therapeutic differentiators within classes, are challenging the prices charged for therapeutics, and are negotiating price concessions based on performance goals.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions both in the United States and in international markets. Third-party coverage and reimbursement for our products or product candidates for which we receive regulatory approval may not be available or adequate in either the United States or international markets, which could have a negative effect on our business, financial condition, results of operations, stock price and prospects.

Assuming coverage is approved, the resulting reimbursement payment rates might not be adequate. If payors subject our product candidates to maximum payment amounts, or impose limitations that make it difficult to obtain reimbursement, providers may choose to use therapies which are less expensive when compared to our product candidates. Additionally, if payors require high copayments, beneficiaries may seek alternative therapies. We may need to conduct postmarketing studies in order to demonstrate the cost effectiveness of any products to the satisfaction of hospitals, other target customers and their third-party payors. Such studies might require us to commit a significant amount of management time and financial and other resources. Our products might not ultimately be considered cost effective. Adequate third party coverage and reimbursement might not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in product development.

In addition, federal programs impose penalties on manufacturers of therapeutics in the form of mandatory additional rebates and/or discounts if commercial prices increase at a rate greater than the Consumer Price Index Urban, and these rebates and/or discounts, which can be substantial, may impact our ability to raise commercial prices. A few states have also passed or are considering legislation intended to prevent significant price increases. Regulatory authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular

medications, which could affect our ability to sell our product candidates profitably. These payors may not view our products, if any, as cost effective, and coverage and reimbursement may not be available to our customers, or may not be sufficient to allow our products, if any, to be marketed on a competitive basis. Cost control initiatives could cause us to decrease, discount, or rebate a portion of the price we, or they, might establish for products, which could result in lower than anticipated product revenues. If the realized prices for our products, if any, decrease or if governmental and other third-party payors do not provide adequate coverage or reimbursement, our prospects for revenue and profitability will suffer.

There may also be delays in obtaining coverage and reimbursement for newly approved therapeutics, and coverage may be more limited than the indications for which the product is approved by the FDA or comparable foreign regulatory authorities. Such delays have made it increasingly common for manufacturers to provide newly approved drugs to patients experiencing coverage delays or disruption at no cost for a limited period in order to ensure that patients are able to access the drug. Moreover, eligibility for reimbursement does not imply that any therapeutic will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for new therapeutics, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary, by way of example, according to the use of the product and the clinical setting in which it is used. Reimbursement rates may also be based on reimbursement levels already set for lower cost products or may be incorporated into existing payments for other services.

In addition, third-party payors are increasingly requiring higher levels of evidence of the benefits and clinical outcomes of new technologies, benchmarking against other therapies, seeking performance-based discounts, and challenging the prices charged. We cannot be sure that coverage will be available for any product candidate that we commercialize and, if available, that the reimbursement rates will be adequate. An inability to promptly obtain coverage and adequate payment rates from both government-funded and private payors for any of our product candidates for which we obtain marketing approval could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

We are subject to new legislation, regulatory proposals and healthcare payor initiatives that may increase our costs of compliance, and adversely affect our ability to market our products, obtain collaborators, and raise capital.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post approval activities and affect our ability to profitably sell any products for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any approved products.

For example, legislative changes have been proposed and adopted since the ACA was enacted in 2010. These changes include, among other things, aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went effective on April 1, 2013. In addition, the American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The Centers for Medicare and Medicaid Services, or CMS, promulgated regulations governing manufacturers' obligations and reimbursement under the Medicaid Drug Rebate Program, and promulgated a regulation that limited Medicare Part B payment to certain hospitals for outpatient drugs purchased under the 340B program. These new laws may result in

additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our products, if approved, and, accordingly, on our results of operations.

We expect that the ACA, as well as other federal and state healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria, increased regulatory burdens and operating costs, decreased net revenue from our biopharmaceutical products, decreased potential returns from our development efforts, and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government healthcare programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from commercializing our products and being able to generate revenue, and we could be prevented from or significantly delayed in achieving profitability.

In addition, there have been a number of other legislative and regulatory proposals aimed at changing the biopharmaceutical industry. For instance, the Drug Quality and Security Act imposes obligations on manufacturers of biopharmaceutical products related to product tracking and tracing. Among the requirements of this legislation, manufacturers are required to provide certain information regarding the product to individuals and entities to which product ownership is transferred, are required to label products with a product identifier, and are required to keep certain records regarding the product. The transfer of information to subsequent product owners by manufacturers is also required to be done electronically. Manufacturers are also being required to verify that purchasers of the manufacturers' products are appropriately licensed. Further, manufactures have product investigation, quarantine, disposition, and FDA, other comparable foreign regulatory authorities, and trading partner notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products that would result in serious adverse health consequences of death to humans, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

Compliance with the federal track and trace requirements may increase our operational expenses and impose significant administrative burdens. As a result of these and other new proposals, we may determine to change our current manner of operation, provide additional benefits or change our contract arrangements, any of which could have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

Our employees, independent contractors, consultants, commercial partners, principal investigators, CMOs, or CROs may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees, independent contractors, consultants, commercial partners, principal investigators, CMOs, or CROs could include intentional, reckless, negligent, or unintentional failures to comply with FDA regulations, comply with applicable fraud and abuse laws, provide accurate information to the FDA, properly calculate pricing information required by federal programs, report financial information or data accurately or disclose unauthorized activities to us. This misconduct could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter this type of misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Moreover, it is possible for a whistleblower to pursue a False Claims Act case against us even if the government considers the claim unmeritorious and declines to intervene, which could require us to incur costs defending against such a claim. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a

significant impact on our business, financial condition, results of operations, stock price and prospects, including the imposition of significant fines or other sanctions.

Violations of or liabilities under environmental, health and safety laws and regulations could subject us to fines, penalties or other costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures, the handling, use, storage, treatment and disposal of hazardous materials and wastes and the cleanup of contaminated sites. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste products. We would incur substantial costs as a result of violations of or liabilities under environmental requirements in connection with our operations or property, including fines, penalties and other sanctions, investigation and cleanup costs and third party claims. Although we generally contract with third parties for the disposal of hazardous materials and wastes from our operations, we cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials.

Our internal computer systems, or those of our third-party CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our development programs.

Our internal computer systems, and those of our CROs, CMOs, information technology suppliers and other contractors and consultants are vulnerable to damage from computer viruses, cyber-attacks and other unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of any of our product candidates could be delayed.

Risks related to our operations

Our financial condition and results of operations could be adversely affected by the recent novel coronavirus disease-2019, or COVID-19, outbreak.

In December 2019, a novel strain of coronavirus, now referred to as COVID-19, surfaced in Wuhan, China. The virus continues to spread globally, including the United States, the United Kingdom and other countries in which we conduct clinical trials, and has been declared a pandemic by the World Health Organization. The impact of this pandemic has been and will likely continue to be extensive in many aspects of society, which has resulted in and will likely continue to result in significant disruptions to the global economy, as well as businesses and capital markets around the world. In an effort to halt the outbreak of COVID-19, many countries, including the United States, the United Kingdom and certain other countries in which we conduct clinical trials, have placed significant

restrictions on travel and business operations and have issued shelter-in-place orders, which have required our employees and clinical trial staff to work remotely and avoid unnecessary travel.

The COVID-19 pandemic is affecting the United States and global economies and may affect our operations and those of third parties on which we rely, including by causing disruptions in our raw material and anti-PD-1 supply, the manufacturing of our product candidates, the commercialization of our product candidates and the conduct of current and future clinical trials. In addition, the COVID-19 pandemic has affected and may continue to affect the operations of the FDA and comparable foreign regulatory authorities, which could result in delays of reviews and approvals, including with respect to RP1 and our other product candidates. The evolving COVID-19 pandemic has also directly or indirectly impacted and is likely to continue to impact the pace of enrollment in our clinical trials as patients may avoid or may not be able to travel to healthcare facilities and physicians' offices unless due to a health emergency and clinical trial staff may no longer be able to get to the clinic. Such facilities and offices have and may continue to be required to focus limited resources on non-clinical trial matters, including treatment of COVID-19 patients, and may not be available, in whole or in part, for clinical trial services. In addition, employee disruptions and remote working environments related to the COVID-19 pandemic and the federal, state and local responses to such virus, could materially impact the efficiency and pace with which we work and develop our product candidates.

The COVID-19 pandemic and the government and public health response continues to rapidly evolve. In light of the COVID-19 pandemic, the FDA has issued a number of new guidance documents. Specifically, as a result of the potential effect of the COVID-19 pandemic on many clinical trial programs in the United States and globally, the FDA issued guidance concerning potential impacts on clinical trial programs, changes that may be necessary to such programs if they proceed, considerations regarding trial suspensions and discontinuations, the potential need to consult with or make submissions to relevant ethics committees, IRBs, and the FDA, the use of alternative drug delivery methods, and considerations with respect the outbreak's impacts on endpoints, data collection, study procedures, and analysis. Additionally, in March 2020, the U.S. Congress passed the Coronavirus Aid, Relief, and Economic Security Act, which includes a number of provisions that are applicable to the pharmaceutical industry.

While the potential economic impact brought by, and the duration and severity of, the COVID-19 pandemic are difficult to assess or predict, the impact of the COVID-19 pandemic on the global financial markets may reduce our ability to access capital, which could negatively impact our short-term and long-term liquidity. Additionally, the stock market has been unusually volatile during the COVID-19 outbreak and such volatility may continue. To date, during certain periods of the COVID-19 pandemic, our stock price fluctuated significantly, and such fluctuation may continue to occur. The ultimate impact of the COVID-19 pandemic on our business will largely depend on future developments, which are highly uncertain, cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions, the ultimate impact on financial markets and the global economy, and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

We do not yet know the full extent of the delays or impacts on our business, financing or clinical trial activities, healthcare systems or the global economy as a whole. However, these effects could have a material impact on our liquidity, capital resources, operations and business and those of the third parties on which we rely. To the extent to COVID-19 pandemic materially impacts our business and financial results, it may also have the effect of significantly heightening many of the other risk described in this "Risk Factors" section.

We will need to expand the size of our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

As our development and commercialization plans and strategies develop, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical, FDA and comparable foreign regulatory review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and
- strengthening our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize RP1 and our other product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services. The services include substantially all aspects of clinical trial management and manufacturing, as well as support for our financial reporting and accounting functions. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, we may not comply with our financial reporting and accounting obligations on a timely basis and we may not be able to obtain marketing approval of RP1 and our other product candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring qualified new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize RP1 and our other product candidates and, accordingly, may not achieve our research, development and commercialization goals.

We are highly dependent on our key personnel, including Philip Astley-Sparke, our Chief Executive Officer; Robert Coffin, Ph.D., our President and Chief Research & Development Officer; and Colin Love, Ph.D., our Chief Operating Officer. If we are not successful in attracting, motivating and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract, motivate and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management and particularly on the services of our founders, as well as our other scientific, manufacturing, quality and medical personnel. Philip Astley-Sparke, our Chief Executive Officer, Robert Coffin, Ph.D., our President and Chief Research & Development Officer, and Colin Love, Ph.D., our Chief Operating Officer, were the founder and senior management team of BioVex Group, Inc., or BioVex, where they invented and developed T-Vec, the only oncolytic immunotherapy to receive FDA approval. BioVex was acquired by Amgen Inc., or Amgen, in 2011. We believe that their drug discovery and development experience, and overall biopharmaceutical company management experience, would be difficult to replace. The loss of the services of our key personnel and any of our other executive officers, key employees, and scientific and

medical advisors, and our inability to find suitable replacements, could result in delays in product development and harm our business. Furthermore, the historical results, past performance and/or acquisitions of companies with which our founders were affiliated, including BioVex, do not necessarily predict or guarantee similar results for our company.

We conduct our operations at our facilities near Boston, Massachusetts and near Oxford, England, each of which are in regions that are home to many other biopharmaceutical companies and many academic and research institutions.

Competition for skilled personnel is intense and the turnover rate can be high, which may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. We expect that we will need to recruit talent from outside of these regions, and doing so may be costly and difficult.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock option grants that vest over time. The value to employees of these equity grants that vest over time may be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Although we have employment agreements with our key employees, these employment agreements generally provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain "key man" insurance policies on the lives of any of these individuals or the lives of any of our other employees.

We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business.

In connection with the audits of our consolidated financial statements as of and for the years ended March 31, 2020, 2019, 2018 and 2017, we identified material weaknesses in our internal control over financial reporting. However, these material weaknesses did not result in a restatement for the years ended March 31, 2020, 2019, 2018 or 2017. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, our stock price and ability to access the capital markets in the future.

The material weaknesses we identified were as follows:

- We did not design or maintain an effective control environment commensurate with our financial reporting requirements. We lacked a sufficient number of professionals with an appropriate level of accounting knowledge, training and experience to appropriately analyze, record and disclose accounting matters timely and accurately. Additionally, the limited personnel resulted in our inability to consistently establish appropriate authorities and responsibilities in pursuit of our financial reporting objectives, as demonstrated by, among other things, our insufficient segregation of duties in our accounting function. This material weakness further contributed to the material weakness below.

- We did not design and maintain formal accounting policies, processes and controls to analyze, account for and disclose complex transactions, including accounting for preferred stock, stock-based compensation, warrant liabilities and leases.

Each of these control deficiencies could result in a misstatement of our accounts or disclosures that would result in a material misstatement of our annual or interim consolidated financial statements that would not be prevented or detected, and accordingly, we determined that these control deficiencies constitute material weaknesses.

These material weaknesses also resulted in adjustments to preferred stock, stock compensation expense, warrant liability and deferred rent in our consolidated financial statements as of and for the year ended March 31, 2017, which were recorded prior to their issuance.

Prior to the completion of our IPO, we were a private company with limited accounting personnel to adequately execute our accounting processes and other supervisory resources with which to address our internal control over financial reporting. We have implemented, and continue to implement, measures designed to improve our internal control over financial reporting and remediate the control deficiencies that led to these material weaknesses. To date, we have hired Jean Franchi, our first Chief Financial Officer, and additional finance and accounting personnel and have engaged a third-party consulting firm to assist us in the design and documentation of appropriate controls. We are continuing these efforts in order to design and implement our financial control environment, including the establishment of controls to account for and disclose complex transactions.

We cannot assure you that the measures we have taken to date, and actions we intend to take in the future, will be sufficient to remediate the control deficiencies that led to these material weaknesses in our internal control over financial reporting or that they will prevent or avoid potential future material weaknesses. In addition, our independent registered public accounting firm has not performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act because no such evaluation has been required. Had our independent registered public accounting firm performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act, additional material weaknesses may have been identified. If we are unable to successfully remediate our existing or any future material weaknesses in our internal control over financial reporting, or identify any additional material weaknesses, the accuracy and timing of our financial reporting may be adversely affected, potentially resulting in restatements of our financial statements, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports and applicable Nasdaq listing requirements, investors may lose confidence in our financial reporting, and our share price may decline as a result.

If we fail to establish and maintain proper and effective internal control over financial reporting our ability to produce accurate and timely financial statements could be impaired.

We are required to maintain internal control over financial reporting. We must perform system and process design evaluation and testing of the effectiveness of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. We continue to be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to incur substantial professional fees and internal costs for our accounting and finance functions, expend significant management efforts, adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls over financial reporting, we may not be able to produce timely and accurate financial statements. If that were to happen, our investors could lose confidence in our reported financial information, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC, Nasdaq or other regulatory authorities.

We believe that any internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. We may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our consolidated financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Our disclosure controls and procedures were not effective as of March 31, 2020, and in any event may not prevent or detect all errors or acts of fraud.

We must design our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. Based on the evaluation of our disclosure controls and procedures as of March 31, 2020, we concluded that, as of March 31, 2020, our disclosure controls and procedures were not effective at the reasonable assurance level as a result of the material weaknesses discussed above. Notwithstanding these material weaknesses, our management has concluded that the financial statements included elsewhere in this Annual Report on Form 10-K present fairly, in all material respects, our financial position, results of operations and cash flows in conformity with generally accepted accounting principles. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

We may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies, or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;

- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party, their regulatory compliance status, and their existing products or product candidates and marketing approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large onetime expenses and acquire intangible assets that could result in significant future amortization expense or intangible asset impairment charges. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business. Any of the foregoing may materially harm our business, financial condition, results of operations, stock price and prospects.

Unfavorable market and economic conditions may have serious adverse consequences on our business, financial condition, results of operations, stock price and prospects.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The most recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including a reduced ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the economic climate and financial market conditions could adversely impact our business.

Global financial markets have been experiencing extreme disruption in recent months, including, among other things, extreme volatility in securities prices. We are unable to predict the likely duration and severity of the current disruptions in financial markets and adverse economic conditions throughout the world. These economic developments affect businesses such as ours and those of third parties on which we rely in a number of ways that could result in unfavorable consequences to us. Current economic conditions or a deepening economic downturn in the United States and elsewhere may reduce our ability to access capital, which could negatively impact our short-term and long-term liquidity.

At March 31, 2020, we had $168.6 million of cash and cash equivalents and short-term investments. Although we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents or short-term investments since that date, we cannot assure you that deterioration of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or short-term investments, or our ability to meet our financing objectives. Furthermore, our stock price may decline due, in part, to the volatility of the stock market and general economic downturns.

Exchange rate fluctuations may materially affect our results of operations and financial conditions.

Owing to the international scope of our operations, fluctuations in exchange rates, particularly between the U.S. dollar and the British pound and the euro, may adversely affect us. Although we are based in the United States, we have significant research and development operations in the United Kingdom, and source third-party manufacturing, consulting and other services in the United Kingdom and the European Union. As a result, our business and the price of our common stock may be affected by fluctuations in foreign exchange rates, which may have a significant impact on our results of operations and cash flows from period to period. Currently, we do not have any exchange rate hedging arrangements in place.

Risks related to our common stock

An active trading market for our common stock may not be sustained.

Our common stock began trading on the Nasdaq Global Select Market on July 20, 2018. Given the limited trading history of our common stock, there is a risk that an active trading market for shares of our common stock may not be sustained. In the absence of an active trading market for shares of our common stock, our stockholders may not be able to sell their common stock at or above the price at which such stockholder acquired our common stock or at the time that they would like to sell.

The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock.

Our stock price has been and is likely to be volatile. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above the price at which it was acquired. The market price for our common stock may be influenced by many factors, including:

- the success of competitive products or technologies;
- results of clinical trials of RP1 and our other product candidates or those of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to the development of RP1 and our other product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or drugs;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions;

- political and economic instability, including the impact of COVID-19, the possibility of an economic recession, international hostilities, acts of terrorism and governmental restrictions, inflation, trade relationships and military and political alliances; and

- the other factors described in this "Risk factors" section.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. From time to time, we may enter into license or collaboration agreements with other companies that include development funding and significant upfront and milestone payments and/or royalties, which may become an important source of our revenue. Accordingly, our revenue may depend on development funding and the achievement of development and clinical milestones under current and any potential future license and collaboration agreements and sales of our products, if approved. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next.

In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award as determined by our board of directors, and recognize the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, including, our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly.

Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

- timing and cost of, and level of investment in, research and development activities relating to our current and any future product candidates, which will change from time to time;

- the total expenses we incur in connection with equipping and operating our manufacturing facility;

- our ability to enroll patients in clinical trials and the timing of enrollment;

- the cost of manufacturing our current and any future product candidates, which may vary depending on the FDA's and comparable foreign regulatory authorities' guidelines and requirements, the quantity of production and the terms of any agreements with manufacturers;

- expenditures that we will or may incur to acquire or develop additional product candidates and technologies;

- the timing and outcomes of clinical and preclinical studies for RP1 and our other product candidates or competing product candidates;

- competition from existing and potential future products that compete with RP1 and our other product candidates, and changes in the competitive landscape of our industry, including consolidation among our competitors or partners;

- any delays in regulatory review or approval of RP1 or our other product candidates;

- the level of demand for RP1 and our other product candidates, if approved, which may fluctuate significantly and be difficult to predict;

- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future products that compete with RP1 and our other product candidates;

- our ability to commercialize RP1 and our other product candidates, if approved, inside and outside of the United States, either independently or working with third parties;
- the success of and our ability to establish and maintain collaborations, licensing or other arrangements;
- our ability to adequately support future growth;
- potential unforeseen business disruptions that increase our costs or expenses;
- political and economic instability, including the impact of the COVID-19 coronavirus, the possibility of an economic recession, international hostilities, acts of terrorism and governmental restrictions, inflation, trade relationships and military and political alliances;
- future accounting pronouncements or changes in our accounting policies; and
- the changing and volatile global economic environment.

These factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue and/or earnings guidance we may provide.

We have broad discretion in how we use our cash, cash equivalents and investments, and may not use these resources effectively, which could affect our results of operations and cause our stock price to decline.

Our management has considerable discretion in the application of our cash, cash equivalents and investments. We intend to use our resources to fund our preclinical and clinical development programs as well as for general corporate purposes, including working capital requirements and other operating expenses. As a result, investors will be relying upon management's judgment with only limited information about our specific intentions for the use of our resources. We may use our resources for purposes that do not yield a significant return or any return at all for our stockholders. In addition, pending their use, we may invest our cash, cash equivalents and investments in a manner that does not produce income or that loses value.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock, which may never occur, as the only way to realize any return on their investment.

Our executive officers, directors, and stockholders and their affiliates who beneficially own more than 5% of our common stock exercise significant influence over our company, which limits your ability to influence corporate matters and could delay or prevent a change in corporate control.

Based on the number of shares outstanding as of March 31, 2020, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned a significant portion of our voting stock and, accordingly, these stockholders will continue to have

significant influence over matters requiring stockholder approval. For example, these stockholders will continue to significantly influence elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

Conflicts of interest may arise because some members of our board of directors are representatives of our principal stockholders.

Certain of our principal stockholders or their affiliates are venture capital funds or other investment vehicles that could invest in entities that directly or indirectly compete with us. As a result of these relationships, when conflicts arise between the interests of the principal stockholders or their affiliates and the interests of other stockholders, members of our board of directors that are representatives of the principal stockholders may not be disinterested. Neither the principal stockholders nor the representatives of the principal stockholders on our board of directors, by the terms of our amended and restated certificate of incorporation, are required to offer us any transaction opportunity of which they become aware and could take any such opportunity for themselves or offer it to their other affiliates, unless such opportunity is expressly offered to them solely in their capacity as members of our board of directors.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the expiration of contractual or legal restrictions on resale lapse, the market price of our common stock could decline. These sales may make it more difficult for us to sell equity or equity related securities in the future at a time and price that we deem appropriate, or to use equity as consideration for future acquisition.

In addition, approximately 10.4 million shares of common stock that are either subject to outstanding options, reserved for future issuance under our equity incentive plans or subject to outstanding warrants are eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

Certain holders of shares of our common stock, or their permitted transferees, are entitled to rights with respect to the registration under the Securities Act of shares of our common stock pursuant to the amended and restated investors' rights agreement by and among us and certain of our stockholders. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates. Any sales of securities by these stockholders could have a material adverse effect on the market price of our common stock.

We may sell up to $75.0 million of shares of our common stock in "at-the-market" offerings pursuant to the sales agreement entered into with SVB Leerink LLC on August 8, 2019. The sale of a substantial number of shares of our common stock pursuant to the sales agreement, or anticipation of such sales, could cause the trading price of our common stock to decline or make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise desire. In addition, issuances of any shares of our common stock sold pursuant to the sales agreement will have a dilutive effect on our existing stockholders.

We incur significant costs as a result of operating as a public company, and our management is required to devote substantial time to compliance initiatives.

As a public company, we incur significant legal, accounting and other expenses. We are subject to the reporting requirements of the Exchange Act, which requires, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act and related SEC and Nasdaq rules impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Emerging growth companies are permitted to implement many of these requirements over a longer period and up to five years from the pricing of our IPO. We intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

The rules and regulations applicable to public companies have substantially increased our legal and financial compliance costs and have made some activities more time consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition, results of operations, stock price and prospects. The increased costs will decrease our net income or increase our net loss and may require us to reduce costs in other areas of our business. For example, these rules and regulations have made it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock relies, in part, on the research and reports that industry or financial analysts publish about us or our business. If one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which, in turn, could cause our stock price to decline.

Antitakeover provisions in our charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws may delay or prevent an acquisition of our company or a change in our management. These provisions include a classified board of directors and the ability of our board of directors to issue preferred stock without stockholder approval. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or DGCL, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with our company. Although we believe these provisions collectively provide for an

opportunity to obtain greater value for stockholders by requiring potential acquirers to negotiate with our board of directors, they would apply even if an offer rejected by our board of directors were considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for our stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

We are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an emerging growth company. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and critical audit matters reporting, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years following the year in which we completed our IPO, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (1) March 31, 2024, (2) the last day of the fiscal year (a) in which we have total annual gross revenue of at least $1.07 billion or (b) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed $700.0 million as of the prior September 30th, and (3) the date on which we have issued more than $1.0 billion in nonconvertible debt during the prior three year period.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company" which would allow us to take advantage of many of the same exemptions from disclosure requirements including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the Jumpstart Our Business Startups Act of 2012, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, changes in rules of U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a breach of fiduciary duty;

- any action asserting a claim against us arising under the DGCL, our amended and restated certificate of incorporation, or our amended and restated bylaws; and

- any action asserting a claim against us that is governed by the internal affairs doctrine.

This exclusive forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for corporate disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers, and other employees. If a court were to find this exclusive forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business.

Item 1B. Unresolved staff comments

None.

Item 2. Properties

Our current corporate headquarters are located in Woburn, Massachusetts. In June 2019, we entered into a lease for this facility, which consists of approximately 18,712 square feet. The term of this lease is approximately ten years, with an option for us to extend the lease by an additional five years. We also lease an approximately 12,000 square-foot facility in Oxfordshire, United Kingdom, containing research and development, laboratory and office space. This lease expires in April 2026 and we have the right to terminate it in April 2021.

In June 2018, we entered into an agreement to lease approximately 63,000 square feet of office, manufacturing and laboratory space in Framingham, Massachusetts. Pursuant to the lease agreement, the lease term commenced in December 2018 and the rent commenced in August 2019. The initial lease term is ten years from the rent commencement date and includes two optional five-year extensions.

We believe that our existing and planned facilities will be adequate to meet our planned needs and that our leases can be renewed, or suitable alternative spaces will be available in the future, on commercially reasonable terms. We do not own any real property.

Item 3. Legal proceedings

We are not currently a party to any material legal proceedings.

Item 4. Mine safety disclosures

Not applicable.

PART II

Item 5. Market for registrant's common equity, related stockholder matters and issuer purchases of equity securities

Our common stock has been listed on the Nasdaq Global Select Market under the symbol "REPL" since July 20, 2018. Prior to that date, there was no public trading market for our common stock.

Holders of common stock

As of May 29, 2020, there were approximately 11 holders of record of our common stock. This number does not reflect beneficial owners whose shares are held in street name.

Dividend policy

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any dividends on our common stock in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, contractual restrictions, business prospects, general business conditions and other factors that our board of directors may deem relevant.

Securities authorized for issuance under equity compensation plans

Information regarding our equity compensation plans and the securities authorized for issuance thereunder is set forth herein under Part III, Item 12 below.

Use of proceeds from registered securities

Shares of our common stock began trading on the Nasdaq Global Select market on July 20, 2018. The offer and sale of all the shares in the initial public offering, or IPO, were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-225846), which was declared effective by the SEC on July 19, 2018. There has been no material change in the planned use of proceeds from our IPO as described in the Prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act on July 23, 2018.

Issuer purchases of equity securities

Not applicable.

Item 6. Selected financial data

You should read the following selected consolidated financial data together with our consolidated financial statements and the related notes appearing at the end of this Annual Report on Form 10-K and the "Management's discussion and analysis of financial condition and results of operations" section of this Annual Report on Form 10-K. We have derived the consolidated statement of operations data for the years ended March 31, 2020, 2019 and 2018 and the consolidated balance sheet data as of March 31, 2020 and 2019 from our audited consolidated financial statements appearing at the end of

this Annual Report on Form 10-K. Our historical results are not necessarily indicative of results that should be expected in any future period.

	Year Ended March 31,		
	2020	2019	2018
Operating expenses:			
Research and development	$ 38,761	$ 22,173	$ 13,516
General and administrative	17,437	8,773	5,713
Total operating expenses	56,198	30,946	19,229
Loss from operations	(56,198)	(30,946)	(19,229)
Other income:			
Research and development incentives	3,084	2,528	2,267
Investment income	2,424	2,585	288
Interest expense on finance lease liability	(1,185)	—	—
Interest expense on debt obligations	(734)	—	—
Change in fair value of warrant liability	—	(5,452)	(972)
Other income (expense), net	(16)	451	(2,056)
Total other income (expense), net	3,573	112	(473)
Net loss attributable to common stockholders	$ (52,625)	$ (30,834)	$ (19,702)
Net loss per share attributable to common stockholders—basic and diluted(1)	$ (1.54)	$ (1.33)	$ (3.96)
Weighted average common shares outstanding—basic and diluted(1)	34,261,548	23,198,400	4,978,539

(1) See Note 10 to our consolidated financial statements appearing at the end of this filing for further details on the calculation of basic and diluted net loss per share attributable to common stockholders.

	March 31,	
	2020	2019
	(in thousands)	
Consolidated Balance Sheet Data:		
Cash, cash equivalents and short-term investments	$ 168,555	$ 134,811
Working capital(1)	162,377	131,096
Total assets	234,097	154,326
Total stockholders' equity	183,718	137,856

(1) We define working capital as current assets less current liabilities.

Item 7. Management's discussion and analysis of financial condition and results of operations

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors. We discuss factors that we believe could cause or contribute to these differences below and elsewhere in this report, including those set forth under Item 1A. "Risk factors" and under "Cautionary note regarding forward-looking statements" in this Annual Report on Form 10-K.

Discussion and analysis of fiscal year ended March 31, 2019 specifically, as well as the year-over-year comparison of our financial performance for the fiscal years ended March 31, 2018 to March 31, 2019, are located in Part II, Item 7—Management's discussion and analysis of financial condition and results of operations in our Annual Report on Form 10-K for the fiscal year ended March 31, 2019, filed with the SEC on June 28, 2019 as amended by Amendment No. 1 thereto filed with the SEC on July 29, 2019, both of which are available on the SEC's website at www.sec.gov.

Overview

Oncolytic immunotherapy, which we intend to establish as the second cornerstone of immune-based cancer treatment, is an emerging class of immuno-oncology therapy, alongside checkpoint blockade, that exploits the ability of certain viruses to selectively replicate in and directly kill tumors, as well as induce a potent, patient-specific, anti-tumor immune response. Such oncolytic, or "cancer killing," viruses have the potential to generate an immune response targeted to an individual patient's particular set of tumor antigens, including neo-antigens that are uniquely present in tumors. Our product candidates incorporate multiple mechanisms of action into a practical "off-the-shelf" approach that is intended to maximize the immune response against a patient's cancer and to offer significant advantages over personalized vaccine approaches. We believe that the bundling of multiple approaches for the treatment of cancer into single therapies will simplify the development path of our product candidates, while also improving patient outcomes at a lower cost to the healthcare system than the use of multiple different drugs.

The foundation of our Immulytic platform consists of a proprietary, engineered strain of herpes simplex virus 1, or HSV-1, that has been "armed" with a fusogenic glycoprotein intended to substantially increase anti-tumor activity. Our Immulytic platform enables us to incorporate various genes into HSV-1 that are intended to further augment the inherent properties of HSV-1 in order to both directly destroy tumor cells and induce an anti-tumor immune response. We currently have three product candidates in our development pipeline, RP1, our lead product candidate, and additionally RP2 and RP3.

We are currently conducting a number of clinical trials of RP1, both as a monotherapy and in combination with anti-PD-1 therapy, with a focus on immune-responsive tumors. We are conducting a randomized, controlled Phase 2 clinical trial of RP1 in approximately 240 patients with cutaneous squamous cell carcinoma, or CSCC, RP1's lead indication. This registration directed clinical trial is evaluating RP1 in combination with cemiplimab, an anti-PD-1 therapy developed by Regeneron Pharmaceuticals, Inc., or Regeneron, versus cemiplimab alone. Regeneron has granted to us a non-exclusive, royalty-free license to cemiplimab for use in this trial, is funding one-half of the clinical trial costs and supplying cemiplimab at no cost to us. We have also opened for enrollment a Phase 1b clinical trial of single agent RP1 in solid organ transplant recipients with CSCC, which we believe to be potentially registrational (in its own right or, subject to discussion with regulatory authorities, following enrollment of additional patients). We have entered into a collaboration with Bristol-Myers Squibb Company, or BMS, under which it has granted us a non-exclusive, royalty-free license to, and is supplying at no cost, its anti-PD-1 therapy, nivolumab, for use in combination with RP1 in a multi-cohort clinical trial. We are currently enrolling a 125-patient extension cohort of RP1 combined with nivolumab in anti-PD-1 refractory cutaneous melanoma. We initiated this cohort after completing enrollment in a prior Phase 2 cohort in the same clinical trial of approximately 30 patients with melanoma. The data generated in the melanoma cohort demonstrated that RP1 combined with nivolumab has the potential to treat anti-PD-1 refractory melanoma. We also believe this cohort to be potentially registrational (in its own right or, subject to discussion with regulatory authorities, following enrollment of additional patients). We continue to enroll patients in other Phase 2 cohorts of approximately 30 patients each, testing RP1 in combination with nivolumab in non-melanoma skin cancers and microsatellite instability high, or MSI-H/dMMR tumors under of our collaboration with

BMS. Due in part to COVID-19 related disruptions, we expect that the non-melanoma skin cancer cohort to be fully accrued by the end of 2020. Similarly, it is likely that accumulating sufficient data to inform a decision as to whether to pursue MSI-H/dMMR tumors into registration-directed development will be delayed into 2021.

In addition, as a result of the recently altered competitive landscape, we recently announced our intention to replace a 30-patient bladder cancer cohort with a cohort of patients with anti-PD-1 refractory non-small cell lung cancer, or NSCLC. We intend to file a protocol amendment with the applicable regulatory authorities in the near term in order to reflect this change.

We are also developing additional product candidates, RP2 and RP3, that have been further engineered to enhance anti-tumor immune responses and are intended to address additional tumor types. In addition to the expression of GALV-GP R(-) and human GM-CSF, RP2 has been engineered to express an antibody-like molecule intended to block the activity of CTLA-4, a protein that inhibits the immune response to tumors. RP3 has also been engineered with the intent to further stimulate an anti-tumor response through activation of the immune co-stimulatory pathways through expression of the ligands for CD40 and 4-1BB.

We initiated the Phase 1 clinical trial of RP2 in October 2019. The Phase 1 clinical trial of RP2 is being conducted as a collaboration with BMS, under which BMS has granted us a non-exclusive, royalty-free license to, and will supply at no cost, nivolumab, for use in combination with RP2. We expect to release initial data from this Phase 1 clinical trial in the second half of 2020. We intend to file an IND and/or foreign equivalents for RP3 and, assuming regulatory clearance, enter clinical development during 2020. IND and/or foreign equivalent enabling studies of RP3 are currently underway.

RP1, RP2 and RP3 are administered by direct injection into solid tumors, guided either visually or by ultrasound or other imaging methods. We believe that direct injection maximizes virus-mediated tumor cell death, provides the most efficient delivery of virus-encoded immune activating proteins into the tumor with the goal of activating systemic immunity, and limits the systemic toxicities that could be associated with intravenous administration. Activation of systemic immunity through local administration is intended to lead to the induction of anti-tumor immune responses leading to clinical response of tumors that have not themselves been injected, which is known as an "abscopal" effect.

We began operations as Replimune Limited, an English limited company that was incorporated in 2015. On July 5, 2017, Replimune Group, Inc., a Delaware corporation, was incorporated and, on July 10, 2017, the shareholders of Replimune Limited effected a share-for-share exchange pursuant to which they exchanged their outstanding shares in Replimune Limited for shares in Replimune Group, Inc., on a one-for-one basis.

In addition, the holders of warrants to purchase shares of series seed preferred stock and stock options to acquire Replimune Limited capital stock canceled their warrants and stock options in Replimune Limited and were issued replacement warrants and stock options to acquire Replimune Group, Inc. capital stock on a one-for-one basis. We refer to these transactions collectively as the reorganization. Upon completion of the reorganization, the historical consolidated financial statements of Replimune Limited became the historical consolidated financial statements of Replimune Group, Inc. because the reorganization was accounted for similar to a reorganization of entities under common control due to the high degree of common ownership of Replimune Limited and Replimune Group, Inc. and lack of economic substance to the transaction. We concluded that the reorganization resulted in no change in the material rights and preferences of each respective class of equity interests and no change in the fair value of each respective class of equity interests before and after the reorganization. On December 8, 2017, Replimune Limited transferred all outstanding shares of its wholly owned subsidiary, Replimune, Inc., to Replimune Group, Inc., a Delaware corporation.

Replimune Group, Inc. is the sole shareholder of Replimune Limited, Replimune, Inc. and Replimune Securities Corporation, a Massachusetts corporation that was incorporated in November 2017.

Financial overview

Since our inception, we have devoted substantially all of our resources to developing our Immulytic platform and our lead product candidate, RP1, building our intellectual property portfolio, conducting research and development of our product candidates, business planning, raising capital and providing general and administrative support for our operations. To date, we have financed our operations primarily with proceeds from the sale of equity securities and to a lesser extent the proceeds from the issuance of debt securities. We do not have any products approved for sale and have not generated any revenue from product sales. On July 24, 2018, we completed our initial public offering, or IPO, of our common stock and issued and sold 6,700,000 shares of our common stock at a public offering price of $15.00 per share, resulting in net proceeds of approximately $93.5 million after deducting underwriting discounts and commissions but before deducting offering costs. On July 30, 2018, we issued and sold an additional 707,936 shares of our common stock at the IPO price of $15.00 per share pursuant to the underwriters' partial exercise of their option to purchase additional shares of common stock, resulting in additional net proceeds of approximately $9.9 million after deducting discounts and commissions but before deducting other offering expenses. On August 8, 2019, we entered into a Loan and Security Agreement with Hercules Capital, Inc., or the Hercules Loan Agreement, pursuant to which we borrowed $10.0 million under a secured term loan facility in the amount of $30.0 million, or the Term Loan Facility. On June 1, 2020 we entered into an amendment to the Hercules Loan Agreement, pursuant to which, among other things, we increased the aggregate principal amount under the Term Loan Facility from $30.0 million to $40.0 million. Also on August 8, 2019, we entered into a Sales Agreement with SVB Leerink LLC, or the Sales Agreement, pursuant to which we may sell, from time to time, at our option, up to an aggregate amount of $75.0 million of shares of our common stock, of which we have sold $4.5 million as of March 31, 2020. On November 18, 2019, we completed a follow-on public stock offering, or the November Offering, of (i) 3,678,031 shares of our common stock at a public offering price of $13.61 per share and (ii) pre-funded warrants to purchase 2,200,000 shares of our common stock at a purchase price of $13.6099 per pre-funded warrant, the public offering price per share of common stock less the $0.0001 per share exercise price of each pre-funded warrant. On December 13, 2019 we sold 838,530 shares of our common stock to the underwriters at the public offering price in connection with the underwriters' partial exercise of their option to purchase additional shares of our common stock. We received aggregate net proceeds of approximately $85.6 million after deducting underwriting discounts, commissions and other offering expenses of approximately $5.8 million.

Since our inception, we have incurred significant operating losses. Our ability to generate product revenue sufficient to achieve profitability will depend on the successful development and eventual commercialization of one or more of our product candidates. Our net losses were $52.6 million and $30.8 million for the years ended March 31, 2020 and 2019, respectively. As of March 31, 2020, we had an accumulated deficit of $112.3 million. These losses have resulted primarily from costs incurred in connection with research and development activities and general and administrative costs associated with our operations. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years.

We anticipate that our expenses and capital requirements will increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials of our product candidates. In addition, we expect to continue to incur additional costs associated with operating as a public company. We expect that our expenses and capital requirements will increase substantially if and as we:

- conduct our current and future clinical trials with RP1;

- progress the clinical development of RP2 and preclinical development of RP3;
- operate our own in-house manufacturing facility;
- seek to identify and develop additional product candidates;
- seek marketing approvals for any of our product candidates that successfully complete clinical trials, if any;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- maintain, expand and protect our intellectual property portfolio;
- hire and retain additional clinical, quality control, scientific and general and administration personnel;
- acquire or in-license other drugs and technologies; and
- add operational, financial and management information systems and personnel, including personnel to support our research and development programs, any future commercialization efforts and operating as a public company.

We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for RP1 or our other product candidates. If we obtain regulatory approval for any of our product candidates and do not enter into a commercialization partnership in any jurisdiction, we expect to incur significant expenses related to developing our internal commercialization capability to support product sales, marketing, and distribution.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances, and marketing, distribution, or licensing arrangements. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back, or discontinue the development and commercialization of one or more of our product candidates.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

As of March 31, 2020, we had cash and cash equivalents and short-term investments of $168.6 million. We believe that our existing cash and cash equivalents and short-term investments will enable us to fund our operating expenses and capital expenditure requirements through at least 12 months from the issuance of the consolidated financial statements included in this Annual Report on Form 10-K.

See "—Liquidity and capital resources" and "Risk factors—Risks related to our financial position and need for additional capital."

Components of our results of operations

Revenue

To date, we have not generated any revenue from product sales as we do not have any approved products and do not expect to generate any revenue from the sale of products in the near future. If our development efforts for RP1 or any other product candidates that we may develop in the future are successful and result in regulatory approval, or if we enter into collaboration or license agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from those collaborations or license agreements.

Operating expenses

Our expenses since inception have consisted solely of research and development costs and general and administrative costs.

Research and development expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our discovery efforts and the development of our product candidates, and include:

- expenses incurred under agreements with third parties, including clinical research organizations, or CROs, that conduct research, preclinical activities and clinical trials on our behalf as well as contract manufacturing organizations, or CMOs, that manufacture our product candidates for use in our preclinical and clinical trials;
- salaries, benefits and other related costs, including stock-based compensation expense, for personnel engaged in research and development functions;
- costs of outside consultants, including their fees, stock-based compensation and related travel expenses;
- the costs of laboratory supplies and acquiring, developing and manufacturing preclinical study and clinical trial materials;
- costs related to compliance with regulatory requirements in connection with the development of our product candidates; and
- facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

These costs will be partially offset by our agreement with Regeneron related to our Phase 2 clinical trial of RP1 in approximately 240 patients with CSCC clinical trial.

We expense research and development costs as incurred. We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our consolidated financial statements as prepaid or accrued research and development expenses.

Our direct external research and development expenses are tracked on a program-by-program basis and consist of costs, such as fees paid to consultants, contractors, CMOs, and CROs in connection with our preclinical and clinical development activities. To date, we have not allocated expenses to our earlier-stage programs for RP2 and RP3. In addition, we do not allocate employee costs, costs associated with our discovery efforts, laboratory supplies, and facilities, including depreciation or other indirect costs, to specific product development programs because these costs are deployed across multiple product development programs and, as such, are not separately classified.

The table below summarizes our research and development expenses by product candidate or development program for each of the periods presented:

	Year Ended March 31,	
	2020	2019
	(Amounts in thousands)	
RP1	$ 14,474	$ 9,685
Unallocated research and development expenses:		
Personnel-related (including stock-based compensation)	14,646	7,534
Other	9,641	4,954
Total research and development expenses	$ 38,761	$ 22,173

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will continue to increase for the foreseeable future as we continue enrollment and initiate additional clinical trials of RP1, pursue initial stages of clinical development of RP2, complete preclinical development of RP3 and continue to discover and develop additional product candidates. The successful development and commercialization of our product candidates is highly uncertain. This is due to the numerous risks and uncertainties associated with product development and commercialization, including the following:

- the scope, rate of progress, expense and results of our ongoing clinical trials , as well future clinical trials or other product candidates and other research and development activities that we may conduct;
- the number and scope of preclinical and clinical programs we decide to pursue;
- our ability to maintain our current research and development programs and to establish new ones;
- uncertainties in clinical trial design and patient enrollment rates;
- the successful completion of clinical trials with safety, tolerability, and efficacy profiles that are satisfactory to the FDA or any comparable foreign regulatory authority;
- the receipt of regulatory approvals from applicable regulatory authorities;
- our success in operating a manufacturing facility, or securing manufacturing supply through relationships with third parties;
- our ability to obtain and maintain patents, trade secret protection, and regulatory exclusivity, both in the United States and internationally;
- our ability to protect our rights in our intellectual property portfolio;
- the commercialization of our product candidates, if and when approved;
- the acceptance of our product candidates, if approved, by patients, the medical community, and third-party payors;
- our ability to successfully develop our product candidates for use in combination with third-party products or product candidates;
- negative developments in the field of immuno-oncology;
- competition with other products; and

- significant and changing government regulation and regulatory guidance.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant trial delays due to patient enrollment or other reasons, we would be required to expend significant additional financial resources and time on the completion of clinical development. We may never succeed in obtaining regulatory approval for any of our product candidates.

General and administrative expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in our executive, finance, corporate and business development and administrative functions. General and administrative expenses also include professional fees for legal, patent, accounting, auditing, tax and consulting services; travel expenses; and facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

We expect that our general and administrative expenses will increase in the future as we increase our general and administrative headcount to support our continued research and development and potential commercialization of our product candidates. We also expect to continue to incur increased expenses associated with being a public company, including costs of accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements; director and officer insurance costs; and investor and public relations costs.

Other income (expense), net

Research and development incentives

Research and development incentives consists of reimbursements of research and development expenditures. We participate, through our subsidiary in the United Kingdom, in the research and development program provided by the United Kingdom tax relief program, such that a percentage of up to 14.5% of our qualifying research and development expenditures are reimbursed by the United Kingdom government, and such incentives are reflected as other income.

Change in fair value of warrant liability

In connection with the issuance of the series seed preferred stock, we issued to the series seed preferred stockholders warrants to purchase shares of series seed preferred stock. Prior to the completion of our IPO, we classified the warrants as a liability on our consolidated balance sheets. We remeasured the warrant liability to fair value at each reporting date and recognized changes in the fair value of the warrant liability as a component of other income (expense), net in our consolidated statements of operations.

Effective upon the completion of our IPO, the warrants to purchase shares of series seed preferred stock became exercisable for shares of common stock instead of shares of preferred stock, and the warrant liability was reclassified to additional paid-in capital. As a result, effective upon the completion of our IPO, we no longer recognize changes in the fair value of the warrant liability as other income (expense), net in our consolidated statements of operations.

Investment income

Investment income consists of income earned on our cash and cash equivalents and short-term investments.

Interest expense on finance lease liability

Interest expense on finance lease liability consists of amortization of finance charges under our financing lease.

Interest expense on debt obligations

Interest expense on debt obligations consists of the amortization of debt discount and cash paid for interest under the Term Loan Facility.

Other income (expense), net

Other income (expense), net consists primarily of realized and unrealized foreign currency transaction gains and losses.

Income taxes

Since our inception and through March 31, 2020, we have not recorded any income tax benefits for the net losses we incurred in each jurisdiction in which we operate, as we believe, based upon the weight of available evidence, that it is more likely than not that all of our net operating loss carryforwards will not be realized.

On December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act, or the Tax Act. The Tax Act includes a number of changes to existing tax law, including, among other things, a permanent reduction in the federal corporate income tax rate from a top marginal rate of 35% to a flat rate of 21%, effective as of January 1, 2018, as well as limitation of the deduction for net operating losses to 80% of annual taxable income and elimination of net operating loss carrybacks, in each case, for losses arising in taxable years beginning after December 31, 2017 (though any such net operating losses may be carried forward indefinitely). Under the Tax Act, our deferred tax assets and liabilities (before valuation allowance) were remeasured at the lower federal tax rate, resulting in an increase to our income tax provision with an equal and offsetting reduction in our valuation allowance. We completed our final determination of the remeasurement of our deferred tax assets and liabilities for the year ended March 31, 2019 under SEC Staff Accounting Bulletin No. 118 and we have not recorded any adjustments to the provisional amounts recorded at March 31, 2018.

Results of operations

Comparison of the years ended March 31, 2020 and 2019

The following table summarizes our results of operations for the years ended March 31, 2020 and 2019:

	Year Ended March 31, 2020	2019	Change
	(Amounts in thousands)		
Operating expenses:			
Research and development	$ 38,761	$ 22,173	$ 16,588
General and administrative	17,437	8,773	8,664
Total operating expenses	56,198	30,946	25,252
Loss from operations	(56,198)	(30,946)	(25,252)
Other income (expense):			
Research and development incentives	3,084	2,528	556
Investment income	2,424	2,585	(161)
Interest expense on finance lease liability	(1,185)	—	(1,185)
Interest expense on debt obligations	(734)	—	(734)
Change in fair value of warrant liability	—	(5,452)	5,452
Other income (expense), net	(16)	451	(467)
Total other income, net	3,573	112	3,461
Net loss	$ (52,625)	$ (30,834)	$ (21,791)

Research and development expenses

	Year Ended March 31, 2020	2019	Change
	(Amounts in thousands)		
Direct research and development expenses by program:			
RP1	$ 14,474	$ 9,685	$ 4,789
Unallocated research and development expenses:			
Personnel-related (including stock-based compensation)	14,646	7,534	7,112
Other	9,641	4,954	4,687
Total research and development expenses	$ 38,761	$ 22,173	$ 16,588

Research and development expenses for the year ended March 31, 2020 were $38.8 million, compared to $22.2 million for the year ended March 31, 2019. The increase of $16.6 million was due primarily to an increase of approximately $4.8 million in direct research costs associated with RP1 and an approximately $11.8 million increase in our unallocated research and development costs. The increase in RP1 costs was due primarily to an increase in clinical trial costs in the year ended March 31, 2020 associated with our ongoing clinical trials.

The increase in unallocated research and development expenses reflected an increase of $7.1 million in personnel-related costs, including stock-based compensation, and an increase of $4.7 million in other costs. The increase in personnel-related costs largely reflected the hiring of additional personnel in our research and development functions as we expanded the development plan for RP1 in multiple indications. Personnel related costs for the years ended March 31, 2020 and 2019 included stock-based compensation expense of $3.7 million and $1.5 million, respectively. Other costs

increased primarily due to potential registrational studies associated with our RP1 development plan with multiple cohorts as well as costs associated with operations of our new manufacturing facility.

General and administrative expenses

General and administrative expenses were $17.4 million for the year ended March 31, 2020, compared to $8.8 million for the year ended March 31, 2019. The increase of $8.7 million primarily reflected increases of $4.7 million in personnel related costs, increases of $2.8 million in facility and other variable costs and increases of $1.1 million in professional fees. The increase in personnel related costs was due to the hiring of additional personnel in our general and administrative functions as we expanded our operations in the United States. The increase in professional fees was due to costs associated with increased spending to build out our information technology capabilities as well a legal and accounting fees related to ongoing business operations. The increase in facility and other variable costs was due primarily to an increase in costs associated with our directors and officers insurance.

Total other income, net

Other income (expense) was $3.6 million for the year ended March 31, 2020, compared to $0.1 million for the year ended March 31, 2019. The increase of $3.5 million was primarily attributable to a $5.5 million charge related to the change in the fair value of the warrant liability in the 2019 fiscal year that did not recur in the 2020 fiscal year and a $0.6 million increase in research and development incentives due to the increase in qualifying research and development expenses. The increase in other income was partially offset by a $1.2 million increase in interest expense related to our finance lease liability as a result of the adoption of ASC 842 during the year ended March 31, 2020, a $0.7 million increase in interest expense on debt obligations related to our Term Loan Facility which was entered into during the year ended March 31, 2020, a $0.5 million decrease in other income due primarily to the changes in foreign currency exchange rates of Great British Pounds to United States Dollars and a $0.2 million decrease in investment income due to fluctuations in the rate of return on investments.

The COVID-19 Pandemic

In December 2019, a novel strain of coronavirus, which causes the disease known as COVID-19, was reported to have surfaced in Wuhan, China. In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic, which continues to spread throughout the U.S. and worldwide. We could be materially and adversely affected by the risks, or the public perception of the risks, related to an epidemic, pandemic, outbreak, or other public health crisis, such as the recent outbreak of COVID-19. We are monitoring the global outbreak and spread of COVID-19 and have taken steps to identify and mitigate the adverse impacts on, and risks to, our business posed by its spread and actions taken by governmental and health authorities to address the COVID-19 pandemic. The spread of COVID-19 has caused us to modify our business practices, including implementing a global work from home policy for certain employees who are able to perform their duties remotely and restricting all nonessential travel, and we expect to continue to take actions as may be required or recommended by government authorities or as we determine are in the best interests of our employees, the patients we serve and other business partners in light of COVID-19. We currently expect the COVID-19 pandemic to delay the timing of patient enrollment and treatment in certain of our ongoing clinical studies. However, the extent of such delays, if any, is currently unknown and has and will likely continue to vary by clinical study site. In addition, we may incur unforeseen costs as a result of disruptions in clinical supply or preclinical study or clinical trial delays. The impact of COVID-19 on our business future results will largely depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions, the ultimate impact on financial markets and the

global economy, and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. See "Risk Factors—Our financial condition and results of operations could be adversely affected by the recent novel coronavirus disease-2019, or COVID-19, outbreak." in Part I, Item 1A of this Annual Report on Form 10-K.

Liquidity and capital resources

Since our inception, we have not generated any revenue from product sales and have incurred significant operating losses and negative cash flows from our operations. We have not yet commercialized any of our product candidates, which are in various phases of preclinical and clinical development, and we do not expect to generate revenue from sales of any products for the foreseeable future, if at all.

Sources of liquidity

To date, we have financed our operations primarily with proceeds from the sale of equity securities and, to a lesser extent, proceeds from the issuance of debt securities. Through March 31, 2020, we had received gross proceeds of approximately $304.0 million from our sales of common stock and preferred stock and $10.0 million from the issuance of debt. As of March 31, 2020, we had cash and cash equivalents and short-term investments of $168.6 million.

On July 24, 2018, we completed our IPO and issued and sold 6,700,000 shares of our common stock at a public offering price of $15.00 per share, resulting in net proceeds of $93.5 million after deducting underwriting discounts and commissions but before deducting offering costs. On July 30, 2018, we issued and sold an additional 707,936 shares of our common stock at the IPO price of $15.00 per share pursuant to the underwriters' partial exercise of their option to purchase additional shares of our common stock, resulting in additional net proceeds of $9.9 million after deducting discounts and commissions but before deducting other offering expenses. On August 8, 2019 and as amended on June 1, 2020, we entered into the Hercules Loan Agreement, pursuant to which we borrowed $10.0 million under the secured Term Loan Facility in the amount of $30.0 million. On August 8, 2019, we entered into the Sales Agreement with SVB Leerink LLC, pursuant to which we may sell, from time to time, at our option, up to an aggregate amount of $75.0 million of shares of our common stock, of which we sold $4.5 million as of March 31, 2020. On November 18, 2019, we closed the November Offering of (i) 3,678,031 shares of its common stock at a public offering price of $13.61 per share and (ii) pre-funded warrants to purchase 2,200,000 shares of our common stock at a purchase price of $13.6099 per pre-funded warrant, the public offering price per share of the common stock less the $0.0001 per share exercise price of each pre-funded warrant. On December 13, 2019, we sold 838,530 shares of our common stock at the public offering price in connection with the underwriters' partial exercise of option to purchase additional shares of our common stock. We received aggregate net proceeds of approximately $85.6 million after deducting underwriting discounts, commissions and other offering expenses of approximately $5.8 million.

Cash flows

The following table summarizes our cash flows for each of the periods presented:

	Year Ended March 31,	
	2020	2019
	(in thousands)	
Net cash used in operating activities	$ (60,552)	$ (25,378)
Net cash used in investing activities	(5,233)	(65,944)
Net cash provided by financing activities	100,166	101,390
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(135)	(839)
Net increase in cash, cash equivalents and restricted cash	$ 34,246	$ 9,229

Operating activities

During the year ended March 31, 2020, net cash used in operating activities was $60.6 million, primarily resulting from our net loss of $52.6 million and net cash used by changes in our operating assets and liabilities of $15.4 million, partially offset by non-cash charges of $7.5 million. Net cash used by changes in our operating assets and liabilities for the year ended March 31, 2020 consisted primarily of a $14.4 million net increase related to the adoption of ASC 842 (including changes in long-term prepaid rent operating lease liabilities, operating lease, right-of-use asset and financing lease, right-of-use-asset), a $3.8 million decrease in accounts payable and a $0.6 million increase in research and development incentives receivable, partially from the United Kingdom government due to the timing and amount of our qualifying expenditures and partially offset by a $0.9 decrease in prepaid expenses and other current assets, and a $2.5 million increase in accrued expenses and other current liabilities. The changes in accounts payable and accrued expenses were primarily due to the timing of vendor invoicing and payments. The decrease in prepaid expenses and other current assets was primarily due to the recognition of prepaid amounts paid to vendors.

During the year ended March 31, 2019, net cash used in operating activities was $25.4 million, primarily resulting from our net loss of $30.8 million and net cash used by changes in our operating assets and liabilities of $1.3 million, partially offset by non-cash charges of $6.7 million. Net cash used by changes in our operating assets and liabilities for the year ended March 31, 2019 consisted primarily of a $0.8 million increase in prepaid expenses and other current assets, a $0.3 million increase in the research and development incentives receivable from the United Kingdom government due to the timing and amount of our qualifying expenditures and a $0.3 million decrease in accrued expenses and other current liabilities, partially offset by a $0.1 million increase in accounts payable. The increase in prepaid expenses and other current assets was primarily due to an increase in amounts paid to vendors. The changes in accounts payable and accrued expenses were primarily due to the timing of vendor invoicing and payments.

Investing activities

During the year ended March 31, 2020, net cash used in investing activities was $5.2 million, consisting of $149.7 million in purchases of available for sale securities and $6.5 million in purchases of property, plant and equipment, partially offset by $151.0 million in proceeds from sales and maturities of short-term investments.

During the year ended March 31, 2019, net cash used in investing activities was $65.9 million, consisting of $189.9 million in purchases of available for sale securities and $2.6 million in purchases of property, plant and equipment, partially offset by $126.6 million in proceeds from maturities of short-term investments.

Financing Activities

During the year ended March 31, 2020, net cash provided by financing activities was $100.2 million, consisting of $57.5 million in net proceeds from the issuance of common stock and $28.2 million in proceeds from issuance of pre-funded warrants to purchase common stock in connection with our follow-on public offering, $10.0 million in proceeds from the issuance of long-term debt, $4.4 million in proceeds from the issuance of common stock through ATM sales and $0.6 million in proceeds from the exercise of stock options, partially offset by $0.4 million in payments of issuance costs and $0.1 million in principal payments of finance lease obligations.

During the year ended March 31, 2019, net cash provided by financing activities was $101.4 million, consisting primarily of net cash proceeds of $103.3 million from our issuance of common stock in connection with our IPO and $0.2 million from the exercise of stock options, partially offset by $2.2 million of payments of issuance costs.

Hercules Loan Agreement

On August 8, 2019 we and certain of our affiliates entered into the Hercules Loan Agreement with Hercules Capital, Inc., or Hercules, pursuant to which, Hercules agreed to make available to us a secured term loan facility in the amount of up to $30 million in the form of term loans, subject to certain terms and conditions. We borrowed $10.0 million at closing under the Hercules Loan Agreement. On June 1, 2020 we entered into an amendment to the Hercules Loan Agreement, pursuant to which, among other things, we increased the aggregate principal amount under the Term Loan Facility from $30.0 million to $40.0 million. Pursuant to the Hercules Loan Agreement, as amended, we may borrow the unused $30.0 million available under the Term Loan Facility in three separate advances. The second advance of up to $10.0 million may be borrowed at our option between October 1, 2020 and December 15, 2020, the third advance of up to $10.0 million may be borrowed at our option between July 1, 2020 and June 30, 2021 and the fourth advance of up to $10.0 million may be borrowed, at our option and subject to the achievement of certain borrowing milestones, between July 1, 2021 and December 15, 2021.

Borrowings under the Hercules Loan Agreement bear interest at a rate per annum equal the greater of either (i) the prime rate as reported in The Wall Street Journal plus 2.75%, or (ii) 8.75%. Under the Hercules Loan Agreement, we were required to make monthly interest-only payments through September 1, 2022, and are required to make equal monthly payments of principal, plus accrued interest, from October 1, 2022 through August 1, 2023. As of March 31, 2020, the outstanding principal amount under the Hercules Loan Agreement was $10.0 million. The term of the Hercules Loan Agreement is four years, ending August 1, 2023.

We may voluntarily prepay all, but not less than all, of the outstanding principal at any time prior to the maturity date, subject to a prepayment fee, which ranges from 1% to 3% of the outstanding principal. A final payment of 4.95% of the aggregate amount of any advances made under the Hercules Loan Agreement.

The Term Loan Facility is secured by substantially all of our assets, excluding our intellectual property, and subject to certain exceptions and exclusions. The Hercules Loan Agreement contains customary affirmative and negative covenants, including restrictions on our ability to pay dividends, incur debt, grant liens, make acquisitions, make loans, dissolving, and entering into leases and asset sales, but does not contain any financial covenants.

Funding requirements

Our plan of operation is to continue implementing our business strategy, continue research and development of RP1 and our other product candidates and continue to expand our research pipeline

and our internal research and development capabilities. We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials of our product candidates. In addition, we expect to continue to incur additional costs associated with operating as a public company. We expect that our expenses will increase substantially if and as we:

- conduct our current and future clinical trials of RP1;
- progress the preclinical and clinical development of RP2 and RP3;
- operate our own in-house manufacturing facility;
- seek to identify and develop additional product candidates;
- seek marketing approvals for any of our product candidates that successfully complete clinical trials, if any;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- until our planned manufacturing facility is fully validated , continued manufacturing by third parties of larger quantities of our product candidates for clinical development.
- maintain, expand and protect our intellectual property portfolio;
- acquire or in-license other drugs and technologies; and
- add operational, financial and management information systems and personnel, including personnel to support our research and development programs, any future commercialization efforts and operations as a public company.

As of March 31, 2020, we had cash and cash equivalents and short-term investments of $168.6 million. We believe that our existing cash and cash equivalents and short-term investments along with our debt commitments will enable us to fund our operating expenses and capital expenditure requirements through 2022.

Because of the numerous risks and uncertainties associated with the development of RP1 and other product candidates and programs, and because the extent to which we may enter into collaborations with third parties for development of our product candidates is unknown, we are unable to estimate the timing and amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidates. Our future capital requirements will depend on many factors, including those described in this section and above under "—Operating expenses—Research and development expenses."

Developing novel biopharmaceutical products, including conducting preclinical studies and clinical trials, is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval for any product candidates or generate revenue from the sale of any products for which we may obtain marketing approval. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of therapies that we do not expect to be commercially available for many years, if ever. Accordingly, we will need to obtain substantial additional funds to achieve our business objectives.

Adequate additional funds may not be available to us on acceptable terms, or at all. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of our equity or convertible debt securities, our shareholders' interest may be diluted, and the terms of these securities may include liquidation or other preferences and anti-dilution protections that could adversely affect the rights of our common stockholder. Additional debt or

preferred equity financing, if available, may involve agreements that include restrictive covenants that may limit our ability to take specific actions, such as incurring debt adversely impact our ability to conduct our business, and may require the issuance of warrants, which could potentially dilute your ownership interest.

If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technology, future revenue streams, research programs, or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or collaborations, strategic alliances or licensing arrangements with third parties when needed, we may be required to delay, limit, reduce and/or terminate our product development programs or any future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Contractual obligations and commitments

The following table summarizes our contractual obligations as of March 31, 2020 and the effects that such obligations are expected to have on our liquidity and cash flows in future periods:

	Payments due by period				
	Total	Less than 1 year	1 to 3 years	4 to 5 years	More than 5 years
	(Amounts in thousands)				
Manufacturing commitments(1)	$ 3,569	$ 3,569	$ —	$ —	$ —
Lease commitments(2)	62,550	3,284	6,223	6,567	46,476
Total	$ 66,119	$ 6,853	$ 6,223	$ 6,567	$ 46,476

(1) Amounts in the table reflect commitments for costs associated with our external CMO, which we engaged to manufacture clinical trial materials.

(2) Amounts in the table reflect minimum payments due under (i) our two operating leases of laboratory and office space in Woburn, Massachusetts and Oxfordshire, United Kingdom, at a monthly commitment of $7 and $31, respectively, and (ii) our financing lease of approximately 63,000 square feet of office, manufacturing and laboratory space in Framingham, Massachusetts. Our lease in Oxfordshire expires in April 2026 and is terminable by us in April 2021. The lease in Woburn, Massachusetts was terminated by the Company in March 2020, prior to the expiration of the lease term. The lease term for our Framingham lease commenced in December 2018. The rent commencement commenced in August 2019. The initial lease term is ten years from the rent commencement date and includes two optional five-year extensions. Annual lease payments during the first year of the lease in Framingham are $2,373 with increases of 3.0% each year. In June 2019, we entered into an agreement to lease approximately 18,700 square feet of office space in Woburn, Massachusetts. Pursuant to the lease agreement, the lease term commenced in August 2019 and the rent commenced in September 2019. The initial lease term is ten years from the rent commencement date and includes an optional five-year extension. Annual lease payments during the first year are $488 with increases of approximately 1.6% each year.

We enter into contracts in the normal course of business with CROs, CMOs and other third parties for clinical trials and preclinical research studies and testing. Manufacturing and research commitments in the preceding table include agreements that are enforceable and legally binding on us and that specify all significant terms, including fixed or minimum quantities to be purchased; fixed, minimum or variable price provisions; and the approximate timing of the transaction. For obligations with cancellation provisions, the amounts included in the preceding table are limited to the non-cancelable portion of the agreement terms or the minimum cancellation fee.

Collaborations

BMS

On February 26, 2018, we entered into a Clinical Trial Collaboration and Supply Agreement with Bristol-Myers Squibb Company, or BMS. Pursuant to the agreement, BMS is providing to us, at no cost, nivolumab, its anti-PD-1 therapy, for use in combination with RP1 in our ongoing Phase 1/2 clinical trial. Under the agreement, we will sponsor, fund and conduct the clinical trial in accordance with an agreed-upon protocol. BMS granted us a non-exclusive, non-transferrable, royalty-free license (with a right to sublicense) under its intellectual property to use nivolumab in the clinical trial and has agreed to supply nivolumab, at no cost to us, for use in the clinical trial. Both parties will own the study data produced in the clinical trial, other than study data related solely to nivolumab, which will belong solely to BMS, or study data related solely to RP1, which will belong solely to us. In January 2020, this agreement was expanded to cover an additional cohort of 125 patients with anti-PD-1 refractory melanoma.

Unless earlier terminated, the agreement will remain in effect until (i) the completion of the clinical trial, (ii) all related clinical trial data have been delivered to both parties and (iii) the completion of any statistical analyses and bioanalyses contemplated by the clinical trial protocol or any analysis otherwise agreed upon by the parties. The agreement may be terminated by either party (i) in the event of an uncured material breach by the other party, (ii) in the event the other party is insolvent or in bankruptcy proceedings or (iii) for safety reasons. Upon termination, the licenses granted to us to use nivolumab in the clinical trial will terminate. The agreement contains representations, warranties, undertakings and indemnities customary for a transaction of this nature.

On April 12, 2019, we entered into a separate agreement with BMS on terms similar to the terms set forth in the agreement described above, pursuant to which BMS will provide, at no cost to us, nivolumab for use in our Phase 1 clinical trial of RP2 in combination with nivolumab.

Regeneron

On May 29, 2018, we entered into a Master Clinical Trial Collaboration and Supply Agreement with Regeneron Pharmaceuticals, Inc., or Regeneron. Pursuant to the agreement we agreed to undertake one or more clinical trials with Regeneron for the administration of our product candidates in combination with cemiplimab, an anti-PD-1 therapy developed by Regeneron, across multiple solid tumor types, the first of which is our ongoing Phase 2 clinical trial testing RP1 in combination with cemiplimab versus cemiplimab alone in patients with CSCC. Each clinical trial will be conducted pursuant to an agreed study plan which, among other things, will identify the name of the sponsor and which party will manage the particular study, and include the protocol, the budget and a schedule of clinical obligations. The first study plan related to the Phase 2 clinical trial in CSCC has been agreed.

Pursuant to the terms of the agreement, each party granted the other party a non-exclusive license of their respective intellectual property and agreed to contribute the necessary resources needed to fulfill their respective obligations, in each case, under the terms of agreed study plans. Development costs of a particular clinical trial will be split equally. The agreement contains representations, warranties, undertakings and indemnities customary for a transaction of this nature. The agreement also contains certain covenants that restrict us from entering into a third-party arrangement with respect to the use of our product candidates in combination with an anti-PD-1 therapy and that restrict Regeneron from entering into a third-party arrangement with respect to the use of cemiplimab in combination with an HSV-1 virus, in each case, for the treatment of a tumor type that is the subject of a clinical trial to which the covenants apply. Unless otherwise mutually agreed in a future study plan, these covenants are only applicable to our ongoing Phase 2 clinical trial in CSCC, and expire upon the one-year anniversary of the commencement of the applicable study plan.

The agreement may be terminated by either party if (i) there is no active study plan for which a final study report has not been completed, (ii) the parties have not entered into a study plan for an additional clinical trial within a period of time after the delivery of the most recent final study report or (iii) in the event of a material breach.

Critical accounting policies and significant judgments and estimates

Our management's discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, costs and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in greater detail in Note 2 to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Accrued research and development expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advanced payments. We make estimates of our accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to us at that time. Examples of estimated accrued research and development expenses include fees paid to:

- CROs in connection with performing research activities and conducting preclinical studies and clinical trials on our behalf;
- CMOs in connection with the production of preclinical and clinical trial materials;
- investigative sites or other service providers in connection with clinical trials;
- vendors in connection with preclinical and clinical development activities; and
- vendors related to product manufacturing and development and distribution of preclinical and clinical supplies.

We base our expenses related to preclinical studies and clinical trials on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple CMOs and CROs that supply, conduct and manage preclinical studies and clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. Payments under some

of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or the amount of prepaid expenses accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

Stock-based compensation

We measure stock-based awards granted to employees and directors based on their fair value on the date of the grant and recognize compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. We have to date only issued stock-based awards with service-based vesting conditions and record the expense for these awards using the straight-line method. The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model, which requires inputs based on certain subjective assumptions, including the expected stock price volatility, the expected term of the option, the risk-free interest rate for a period that approximates the expected term of the option, and our expected dividend yield. See Note 9 to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K for more information. Forfeitures are accounted for as they occur. The fair value of each stock-based award is estimated on the date of grant based on the fair value of our common stock on that same date.

Prior to the adoption of ASC 2018-07 on April 1, 2019, for stock-based awards granted to consultants and non-employees, we recognize compensation expense over the period during which services are rendered by such non-employees and consultants until completed. At the end of each financial reporting period prior to completion of the service, the fair value of these awards is remeasured using the then-current fair value of our common stock and updated assumption inputs in the Black-Scholes option pricing model.

After the adoption of ASC 2018-07, for stock-based awards granted to consultants and non-employees, we measure stock-based these awards based on their fair value on the date of the grant and recognizes compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. We have to date only issued stock-based awards with service-based vesting conditions and record the expense for these awards using the straight-line method. The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model, which requires inputs based on certain subjective assumptions, including the expected stock price volatility, the expected term of the option, the risk-free interest rate for a period that approximates the expected term of the option, and our expected dividend yield.

We classify stock-based compensation expense in our consolidated statements of operations in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

Off-balance sheet arrangements

We did not have any off-balance sheet arrangements during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Recently issued accounting pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

Emerging growth company status

As an "emerging growth company," the Jumpstart Our Business Startups Act of 2012 permits us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have irrevocably elected to "opt out" of this provision and, as a result, we will comply with new or revised accounting standards when they are required to be adopted by public companies that are not emerging growth companies.

Item 7A. Quantitative and qualitative disclosures about market risks

Interest rate sensitivity

As of March 31, 2020, we had cash and cash equivalents and short-term investments of $168.6 million, which consisted of cash equivalents, commercial paper, commercial debt securities and U.S. Treasury securities. Interest income is sensitive to changes in the general level of interest rates; however, due to the nature of these investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our investment portfolio.

As of March 31, 2020, we had $10.0 million of borrowings outstanding under our Term Loan Facility. Borrowings under our Term Loan Facility bear interest at variable rates. Based on the principal amounts outstanding as of March 31, 2020, an immediate 10% change in the interest rate would not have a material impact on our debt related obligations, financial position or results of operations.

Foreign currency exchange risk

Our headquarters are located in the United States, where the majority of our general and administrative expenses are incurred in U.S. dollars. The majority of our research and development costs are incurred by our subsidiary in Oxfordshire, United Kingdom, whose functional currency is the British pound. We are exposed to foreign exchange rate risk. During the years ended March 31, 2020, 2019 and 2018, we recognized foreign currency transaction gains (losses) of $(16,000), $0.5 million and $(2.1) million, respectively. These gains (losses) are primarily related to unrealized and realized foreign currency gains and losses as a result of transactions entered into by our United Kingdom subsidiary in currencies other than the British pound, primarily the euro. These foreign currency transaction gains (losses) were recorded as a component of other income (expense), net in our consolidated statements of operations. We believe that a 10% change in the exchange rate between the British pound and the euro would not have a material impact on our financial position or results of operations.

As we continue to grow our business, our results of operations and cash flows will be subject to fluctuations due to changes in foreign currency exchange rates, which could adversely impact our results of operations. To date, we have not entered into any foreign currency hedging contracts to mitigate our exposure to foreign currency exchange risk.

Item 8. Financial statements and supplementary data

See the consolidated financial statements filed as part of this Annual Report on Form 10-K as listed under Item 15 below.

Item 9. Changes in and disagreements with accountants on accounting and financial disclosures

Not Applicable.

Item 9A. Controls and procedures

Evaluation of disclosure controls and procedures

The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, refers to controls and procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that such information is accumulated and communicated to a company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

In designing and evaluating our disclosure controls and procedures, management recognizes that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a control system, misstatements due to error or fraud may occur and not be detected.

Based on the evaluation of our disclosure controls and procedures as of March 31, 2020, our Chief Executive Officer and Chief Financial Officer have concluded that, as of March 31, 2020, our disclosure controls and procedures were not effective at the reasonable assurance level as a result of the material weaknesses discussed below. Notwithstanding these material weaknesses, our Chief Executive Officer and Chief Financial Officer concluded that the financial statements included elsewhere in this Annual Report on Form 10-K present fairly, in all material respects, our financial position, results of operations and cash flows in conformity with generally accepted accounting principles, or GAAP.

Management's report on internal control over financial reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act). Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

(i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets;

(ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and

(iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management of the Company has assessed the effectiveness of the Company's internal control over financial reporting as of March 31, 2020. In making its assessment of internal control over financial reporting, management used the criteria established in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In making the assessment, we identified material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. The material weaknesses that we identified were as follows:

We did not design or maintain an effective control environment commensurate with our financial reporting requirements. We lacked a sufficient number of professionals with an appropriate level of accounting knowledge, training and experience to appropriately analyze, record and disclose accounting matters timely and accurately. Additionally, the limited personnel resulted in our inability to consistently establish appropriate authorities and responsibilities in pursuit of our financial reporting objectives, as demonstrated by, among other things, our insufficient segregation of duties in our accounting function. This material weakness further contributed to the material weakness below.

We did not design and maintain formal accounting policies, processes and controls to analyze, account for and disclose complex transactions, including accounting for preferred stock, stock-based compensation, warrant liabilities and leases.

These control deficiencies did not result in a misstatement to our annual or interim financial statements. However, each of these control deficiencies could result in a misstatement of the aforementioned accounts or disclosures that would result in a material misstatement of our annual or interim consolidated financial statements that would not be prevented or detected, and accordingly, we determined that these control deficiencies each constitute material weaknesses.

Because of these material weaknesses, management concluded that the Company did not maintain effective internal control over financial reporting as of March 31, 2020.

This annual report does not include an audit report of the Company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to audit by the Company's registered public accounting firm pursuant to rules of the Securities and Exchange Commission that permit the Company to provide only management's report in this annual report.

Remediation activities

We have identified and implemented, and continue to implement, certain remediation efforts to improve the effectiveness of our internal control over financial reporting and disclosure controls and procedures. These remediation efforts are ongoing. The following remedial actions have been completed as of the year ended March 31, 2020:

- We hired a Chief Financial Officer and other additional full-time accounting resources with appropriate levels of experience and reallocated responsibilities across the accounting

organization to provide for segregation of duties and that the appropriate level of knowledge and experience is applied based on risk and complexity of transactions and tasks under review.

- We have increased the level of involvement and oversight from our new Chief Financial Officer and will maintain this level of oversight until the control environment and risk assessment processes have matured.

- We engaged a professional accounting services firm to assist us in the design and documentation of our formal policies, processes and internal controls for complying with the Sarbanes-Oxley Act, including formal policies, processes and internal controls to analyze, account for and disclose complex accounting transactions.

- We have performed a detailed financial reporting risk assessment to identify areas that require improvement and developed and implemented plans to address these areas; as a result, we have improved documentation of account reconciliations, and management review procedures and enhanced our GAAP training initiatives in key areas.

The process of implementing an effective financial reporting system is a continuous effort that requires us to anticipate and react to changes in our business and the economic and regulatory environments and to expend significant resources to maintain a financial reporting system that is adequate to satisfy our reporting obligations. As we continue to evaluate and take actions to improve our internal control over financial reporting, we may take additional actions to address control deficiencies or modify certain of the remediation measures described above.

While progress has been made to enhance our internal control over financial reporting, we are still in the process of implementing, documenting and testing these processes, procedures and controls. Additional time is required to complete implementation and to assess and ensure the sustainability of these procedures. We will continue to devote significant time and attention to these remedial efforts. However, the material weaknesses cannot be considered remediated until the applicable remedial controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively.

Changes in internal control over financial reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fourth quarter of the fiscal year ended March 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other information

None.

PART III

Item 10. Directors, executive officers and corporate governance

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended March 31, 2020.

The text of our Code of Business Conduct and Ethics, which applies to our directors and employees (including our principal executive officer, principal financial officer, and principal accounting officer or controller, and persons performing similar functions), is posted in the "Corporate Governance" section of our website, www.replimune.com. A copy of the Code of Business Conduct and Ethics can be obtained free of charge on our website. We intend to disclose on our website any amendments to, or waivers from, our Code of Business Conduct and Ethics that are required to be disclosed pursuant to the rules of the Securities and Exchange Commission and Nasdaq.

Item 11. Executive compensation

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange commission not later than 120 days after the close of our fiscal year ended March 31, 2020.

Item 12. Security ownership of certain beneficial owners and management and related stockholder matters

Securities authorized for issuance under equity compensation plans

The following table provides information as of March 31, 2020, regarding our common stock that may be issued under (1) the 2017 Equity Compensation Plan, or the 2017 Plan; (2) the 2018 Omnibus Incentive Compensation Plan, or the 2018 Plan; or (3) the Employee Stock Purchase Plan, or the ESPP.

Plan category:	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Available for Future Issuance Under Equity Compensation Plans
Equity compensation plans approved by stockholders			
2017 Plan	2,128,824	$ 2.76	—
2018 Plan	2,835,557	$ 15.06	2,122,012
ESPP	—	—	665,181
Total	4,964,381		2,787,193

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange commission not later than 120 days after the close of our fiscal year ended March 31, 2020.

Item 13. Certain relationships and related transactions, and director independence

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities

and Exchange commission not later than 120 days after the close of our fiscal year ended March 31, 2020.

Item 14. Principal accountant fees and services

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange commission not later than 120 days after the close of our fiscal year ended March 31, 2020.

PART IV

Item 15. Exhibits and financial statement schedules

(a) 1. Consolidated Financial Statements.

For a list of the consolidated financial statements included herein, see Index on page F-1 of this report.

2. Financial Statement Schedules.

All required information is included in the financial statements or notes thereto.

3. List of Exhibits.

The documents listed in the Exhibit index immediately preceding the signature page of this Annual Report on Form 10-K are incorporated by reference or are filed or furnished with this Annual Report on Form 10-K, in each case as indicated therein.

Item 16. 10-K summary

None.

Exhibit index

Exhibit Number	Exhibit Description	Incorporated by Reference		
		Form	Date	Number
3.1*	Third Amended and Restated Certificate of Incorporation of Replimune Group, Inc. (conformed to include the Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation filed on September 9, 2019).			
3.2	Amended and Restated By-laws of Replimune Group, Inc.	8-K	July 24, 2018	3.2
4.1	Form of Common Stock Certificate of the Registrant.	S-1/A	July 10, 2018	4.1
4.2	Amended and Restated Investors' Rights Agreement, dated July 10, 2017, by and among the Registrant and the investors set forth therein.	S-1	June 22, 2018	4.2
4.3*	Description of the Registrant's Securities registered pursuant to Section 12 of the Securities Exchange Act of 1934.			
4.4	Form of Pre-Funded Warrant.	8-K	November 18, 2019	4.1
4.5	Form of Indenture to be entered into between the Registrant and a trustee acceptable to the Registrant.	S-3	August 8, 2019	4.4
10.1	Form of Indemnification Agreement by and between the Registrant and its directors and officers.	S-1/A	July 10, 2018	10.1
10.2†	2017 Equity Compensation Plan and Sub-Plan for U.K. Employees and forms of agreements thereunder.	S-1/A	June 26, 2018	10.2
10.3†	2018 Omnibus Incentive Compensation Plan and Sub-Plan for U.K. Employees and forms of agreements thereunder.	S-1/A	July 10, 2018	10.3
10.4†	Employee Stock Purchase Plan.	S-1/A	July 10, 2018	10.4
10.5†	Employment Agreement, effective as of October 1, 2015, by and between Robert Coffin and Replimune, Inc.	S-1	June 22, 2018	10.5
10.6†	Employment Agreement, effective as of October 1, 2015, by and between Philip Astley-Sparke and Replimune, Inc.	S-1	June 22, 2018	10.6
10.7†	Employment Agreement, effective as of November 1, 2015, by and between Pamela Esposito and Replimune, Inc.	S-1	June 22, 2018	10.7
10.8†	Employment Agreement, dated as of June 22, 2018, by and between Howard Kaufman and Replimune, Inc.	S-1/A	July 10, 2018	10.8
10.9†	Employment Agreement, dated as of September 16, 2015, by and between Colin Love and Replimune Limited.	S-1/A	July 10, 2018	10.9
10.10†	Employment Agreement, dated as of May 8, 2019, by and between Stephen Gorgol and Replimune, Inc.	10-K	June 28, 2019	10.10

Exhibit Number	Exhibit Description	Incorporated by Reference		
		Form	Date	Number
10.11†	Employment Agreement, dated as of November 27, 2019, by and between Jean Franchi and Replimune, Inc.	8-K	December 9, 2019	10.1
10.12†	Separation Agreement and Release, dated as of December 23, 2019, by and between Howard Kaufman and Replimune, Inc.	10-Q	February 13, 2020	10.2
10.13†*	Separation Agreement and Release, dated as of March 30, 2020, by and between Stephen Gorgol and Replimune, Inc.			
10.14	Lease, dated as of April 1, 2016, by and between Cummings Properties, LLC and the Registrant.	S-1	June 22, 2018	10.8
10.15	Lease, dated as of April 4, 2016, by and between MEPC Milton Park No. 1 Limited and MEPC Milton Park No. 2 Limited, and Replimune Limited.	S-1	June 22, 2018	10.9
10.16‡	Clinical Trial Collaboration and Supply Agreement, dated as of February 26, 2018, by and between Bristol-Myers Squibb Company and the Registrant.	S-1/A	July 10, 2018	10.12
10.17‡	Master Clinical Trial Collaboration and Supply Agreement, dated as of May 29, 2018, by and between Regeneron Pharmaceuticals, Inc. and the Registrant.	S-1/A	July 17, 2018	10.13
10.18	Indenture of Lease, dated as of June 22, 2018, by and between CRP/King 33 NY Ave. Owner, L.L.C. and the Registrant.	S-1	June 22, 2018	10.12
10.19	Lease, dated as of June 7, 2019, by and between ND/CR Unicorn LLC and the Registrant.	8-K	June 13, 2019	10.1
10.20	Loan and Security Agreement by and among Replimune Group, Inc., Replimune, Inc., Replimune Limited and Hercules Capital, Inc., dated August 7, 2019.	8-K	August 8, 2019	10.2
10.21*	First Amendment to Loan and Security Agreement by and among Replimune Group, Inc., Replimune, Inc., Replimune Limited and Hercules Capital, Inc., dated June 1, 2020.			
10.22*‡	Clinical Trial Collaboration and Supply Agreement (RP-2), dated April 12, 2019, by and between Bristol-Myers Squibb Company and Replimune, Inc.			
21.1*	Subsidiaries of the Registrant.			
23.1*	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.			
31.1*	Certification of the Chief Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350).			

Exhibit Number	Exhibit Description	Incorporated by Reference		
		Form	Date	Number
31.2*	Certification of the Chief Accounting Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350).			
32.1**	Certification of the Chief Executive Officer, as required by Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350).			
32.2**	Certification of the Chief Accounting Officer, as required by Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350).			
101.INS*	XBRL Instance Document.			
101.SCH*	XBRL Taxonomy Extension Schema Document.			
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document.			
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document.			
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document.			
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document.			

* Filed herewith.

** Furnished and not filed herewith.

† Indicates management contract or compensatory plan.

‡ Certain confidential portions of this exhibit were omitted in accordance with Item 601(b)(10) of Regulation S-K.

Signatures

Pursuant to the requirements of Section 13 or 15(d) of the Securities Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

REPLIMUNE GROUP, INC.

Date: June 3, 2020

By: /s/ PHILIP ASTLEY-SPARKE

Philip Astley-Sparke
Chief Executive Officer and Director

Pursuant to the requirements of the Securities Act of 1934, this report has been signed by the following persons in the capacities and on the dates indicated.

Name	Title	Date
/s/ PHILIP ASTLEY-SPARKE Philip Astley-Sparke	Chief Executive Officer and Director (Principal Executive Officer)	June 3, 2020
/s/ JEAN FRANCHI Jean Franchi	Chief Financial Officer, Treasurer, Secretary, and Compliance Officer (Principal Financial and Accounting Officer)	June 3, 2020
/s/ ROBERT COFFIN Robert Coffin	President and Chief Research & Development Officer and Director	June 3, 2020
/s/ KAPIL DHINGRA Kapil Dhingra	Director	June 3, 2020
/s/ HYAM LEVITSKY Hyam Levitsky	Director	June 3, 2020
/s/ PAOLO PUCCI Paolo Pucci	Director	June 3, 2020
/s/ JASON RHODES Jason Rhodes	Director	June 3, 2020

Name	Title	Date
/s/ JOSEPH SLATTERY Joseph Slattery	Director	June 3, 2020
/s/ OTELLO STAMPACCHIA Otello Stampacchia	Director	June 3, 2020
/s/ SANDER SLOOTWEG Sander Slootweg	Director	June 3, 2020
/s/ DIETER WEINAND Dieter Weinand	Director	June 3, 2020

REPLIMUNE GROUP, INC.

Financial Statements

For the Years Ended March 31, 2020, 2019 and 2018

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of
Replimune Group, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Replimune Group, Inc. and its subsidiaries (the "Company") as of March 31, 2020 and 2019, and the related consolidated statements of operations, of comprehensive loss, of convertible preferred stock and stockholders' equity (deficit) and of cash flows for each of the three years in the period ended March 31, 2020, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of March 31, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended March 31, 2020 in conformity with accounting principles generally accepted in the United States of America.

Change in Accounting Principle

As discussed in Note 2 to the consolidated financial statements, the Company changed the manner in which it accounts for leases on April 1, 2019.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP
Boston, Massachusetts
June 3, 2020

We have served as the Company's auditor since 2018.

REPLIMUNE GROUP, INC.

CONSOLIDATED BALANCE SHEETS

(Amounts in thousands, except share and per share amounts)

	March 31, 2020	March 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 59,500	$ 25,704
Short-term investments	109,055	109,107
Research and development incentives receivable	2,962	2,474
Prepaid expenses and other current assets	2,734	3,696
Total current assets	174,251	140,981
Property, plant and equipment, net	6,860	12,159
Restricted cash	1,636	1,186
Right-to-use asset—operating leases	4,425	—
Right-to-use asset—financing leases	46,925	—
Total assets	$ 234,097	$ 154,326
Liabilities, Convertible Preferred Stock and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,434	$ 7,084
Accrued expenses and other current liabilities	5,156	2,801
Operating lease liabilities, current	873	—
Financing lease liabilities, current	2,411	—
Total current liabilities	11,874	9,885
Deferred rent, net of current portion	—	24
Financing obligation	—	6,561
Long term debt, net of debt discount	9,801	—
Operating lease liabilities, non-current	3,737	—
Financing lease liabilities, non-current	24,967	—
Total liabilities	50,379	16,470
Commitments and contingencies (Note 12)		
Stockholders' Equity		
Common stock, $0.001 par value; 150,000,000 shares authorized as of March 31, 2020 and 2019; 36,668,743 and 31,656,950 shares issued and outstanding as of March 31, 2020 and 2019, respectively	37	32
Additional paid-in capital	296,961	198,645
Accumulated deficit	(112,298)	(59,766)
Accumulated other comprehensive loss	(982)	(1,055)
Total stockholders' equity	183,718	137,856
Total liabilities, convertible preferred stock and stockholders' equity	$ 234,097	$ 154,326

The accompanying notes are an integral part of these consolidated financial statements.

REPLIMUNE GROUP, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(Amounts in thousands, except share and per share amounts)

	Year Ended March 31,		
	2020	2019	2018
Operating expenses:			
Research and development	$ 38,761	$ 22,173	$ 13,516
General and administrative	17,437	8,773	5,713
Total operating expenses	56,198	30,946	19,229
Loss from operations	(56,198)	(30,946)	(19,229)
Other income (expense):			
Research and development incentives	3,084	2,528	2,267
Investment income	2,424	2,585	288
Interest expense on finance lease liability	(1,185)	—	—
Interest expense on debt obligations	(734)	—	—
Change in fair value of warrant liability	—	(5,452)	(972)
Other income (expense)	(16)	451	(2,056)
Total other income (expense), net	3,573	112	(473)
Net loss attributable to common stockholders	$ (52,625)	$ (30,834)	$ (19,702)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.54)	$ (1.33)	$ (3.96)
Weighted average common shares outstanding, basic and diluted	34,261,548	23,198,400	4,978,539

The accompanying notes are an integral part of these consolidated financial statements.

REPLIMUNE GROUP, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(Amounts in thousands)

	Year Ended March 31,		
	2020	2019	2018
Net loss	$ (52,625)	$ (30,834)	$ (19,702)
Other comprehensive loss:			
Foreign currency translation gain (loss)	(236)	(897)	2,376
Net unrealized gain (loss) on short-term investments, net of tax	309	80	(65)
Comprehensive loss	$ (52,552)	$ (31,651)	$ (17,391)

The accompanying notes are an integral part of these consolidated financial statements.

REPLIMUNE GROUP, INC.

CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)

(Amounts in thousands, except share amounts)

	Convertible preferred stock		Common stock		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total stockholders' equity (deficit)
	Shares	Amount	Shares	Amount				
Balances as of March 31, 2017	1,064,553	$ 31,609	4,973,439	$ 5	$ 259	$ (9,230)	$ (2,549)	$ (11,515)
Issuance of series B convertible preferred stock, net of $198 issuance costs	861,415	54,752	—	—	—	—	—	—
Issuance of common A stock	—	—	26,258	—	—	—	—	—
Foreign currency translation adjustment	—	—	—	—	—		2,376	2,376
Unrealized loss on short-term investments, net of tax	—	—	—	—	—	—	(65)	(65)
Stock options in exchange for consulting services	—	—	7,788	—	26	—	—	26
Stock-based compensation expense	—	—	—	—	812	—	—	812
Net loss	—	—	—	—	—	(19,702)	—	(19,702)
Balances as of March 31, 2018	1,925,968	86,361	5,007,485	5	1,097	(28,932)	(238)	(28,068)
Conversion of convertible preferred stock into common stock upon closing of initial public offering	(1,925,968)	(86,361)	19,157,360	19	86,342	—	—	86,361
Conversion of convertible preferred stock warrants into common stock warrants	—	—	—	—	7,094	—	—	7,094
Repurchase of class A common stock upon closing of initial public offering	—	—	(26,258)	—	—	—	—	—
Issuance of common stock upon closing of initial public offering, net of issuance costs and underwriter fees of $9,935	—	—	7,407,936	7	101,177	—	—	101,184
Stock-based compensation expense	—	—	—	—	2,730	—	—	2,730
Exercise of stock options	—	—	110,427	1	205	—	—	206
Unrealized gain on short-term investments	—	—	—	—	—	—	80	80
Foreign currency translation adjustment	—	—	—	—	—	—	(897)	(897)
Net loss	—	—	—	—	—	(30,834)	—	(30,834)
Balances as of March 31, 2019	—	—	31,656,950	32	198,645	(59,766)	(1,055)	137,856
Issuance of common stock through ATM sales, net of offering costs	—	—	287,559	—	4,431	—	—	4,431
Issuance of common shares upon closing of follow-on public offering, net of issuance costs and underwriter fees of $4,017	—	—	4,516,561	5	57,448	—	—	57,453
Issuance of prefunded warrants to purchase common stock, net of issuance costs and underwriter fees of $1,797	—	—	—	—	28,145	—	—	28,145
Foreign currency translation adjustment	—	—	—	—	—	—	(236)	(236)
Unrealized gain on short-term investments	—	—	—	—	—	—	309	309
Exercise of stock options	—	—	207,673	—	551	—	—	551
Stock-based compensation expense	—	—	—	—	7,741	—	—	7,741
Impact of adoption of ASC 842						93		93
Net loss	—	—	—	—	—	(52,625)	—	(52,625)
Balances as of March 31, 2020	$ —	$ —	36,668,743	$ 37	$ 296,961	$ (112,298)	$ (982)	$ 183,718

The accompanying notes are an integral part of these consolidated financial statements.

REPLIMUNE GROUP, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Amounts in thousands)

	Year Ended March 31,		
	2020	2019	2018
Cash flows from operating activities:			
Net loss	$ (52,625)	$ (30,834)	$ (19,702)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation expense	7,741	2,730	812
Depreciation and amortization	533	148	109
Change in fair value of warrant liability	—	5,452	972
Stock options in exchange for consulting services	—	—	26
Net amortization of premiums and discounts on short-term investments	(945)	(1,715)	(123)
Noncash rent expense	—	93	—
Noncash interest expense	156	—	—
Changes in operating assets and liabilities:			
Research and development incentives receivable	(628)	(255)	(767)
Prepaid expenses and other current assets	933	(801)	(305)
Operating lease, right-to-use-asset	588	—	—
Finance lease, right-to-use-asset	1,274	—	—
Long term prepaid rent	(15,787)	—	—
Accounts payable	(3,821)	120	1,596
Accrued expenses and other current liabilities	2,479	(292)	1,393
Operating lease liabilities	(450)	—	—
Deferred rent	—	(24)	(25)
Net cash used in operating activities	(60,552)	(25,378)	(16,014)
Cash flows from investing activities:			
Purchases of property, plant and equipment	(6,540)	(2,600)	(136)
Purchase of short-term investments	(149,682)	(189,931)	(52,463)
Proceeds from sales and maturities of short-term investments	150,989	126,587	8,553
Net cash used in investing activities	(5,233)	(65,944)	(44,046)
Cash flows from financing activities:			
Proceeds from issuance of series B convertible preferred stock, net of issuance costs	—	—	54,752
Proceeds from issuance of common stock in initial public offering, net of underwriting fees and discounts	—	103,341	—
Proceeds from issuance of common stock in follow-on public offering, net of underwriting fees and discounts	57,453	—	—
Proceeds from issuance of prefunded warrants to purchase common stock, net of underwriting fees and discounts	28,145	—	—
Proceeds from issuance of common stock through ATM sales	4,431	—	—
Proceeds from long-term debt	10,000	—	—
Exercise of stock options	551	206	—
Payment of issuance costs	(355)	(2,157)	—
Principal payment of finance lease obligation	(59)	—	—
Net cash provided by financing activities	100,166	101,390	54,752
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(135)	(839)	2,297
Net increase (decrease) in cash, cash equivalents and restricted cash	34,246	9,229	(3,011)
Cash, cash equivalents and restricted cash at beginning of year	26,890	17,661	20,672
Cash, cash equivalents and restricted cash at end of year	$ 61,136	$ 26,890	$ 17,661
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ 578	$ —	$ —
Supplemental disclosure of non-cash investing and financing activities:			
Net unrealized gain (loss) on short term investments	$ 309	$ 80	$ (65)
Purchases of property and equipment included in accounts payable	$ 209	$ 5,047	$ —
Conversion of preferred stock into common stock	$ —	$ 86,361	$ —
Conversion of convertible preferred stock warrants into common stock warrants	$ —	$ 7,094	$ —
Amounts capitalized under built-to-suit lease transaction	$ —	$ 4,292	$ —
Lease assets obtained in exchange for new financing lease liabilities	$ 48,224	$ —	$ —
Lease assets obtained in exchange for new operating lease liabilities	$ 5,152	$ —	$ —
Adjustment for non-cash lease termination	$ 117	$ —	$ —

The accompanying notes are an integral part of these consolidated financial statements.

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share amounts)

1. Nature of the business

Replimune Group, Inc. (the "Company") is a clinical-stage biotechnology company focused on the development of oncolytic immunotherapies to treat cancer.

Replimune Limited ("Replimune UK") was incorporated in 2015 under the laws of England, and was the sole shareholder of Replimune, Inc. ("Replimune US"), a Delaware corporation. On July 5, 2017, Replimune Group, Inc., a Delaware corporation, was incorporated and on July 10, 2017 the shareholders of Replimune UK effected a share-for-share exchange pursuant to which they exchanged their outstanding shares in Replimune UK for shares in Replimune Group, Inc., on a one-for-one basis. In addition, the holders of warrants and stock options to purchase Replimune UK capital stock canceled their warrants to purchase shares of series seed preferred stock and stock options in Replimune UK and were issued replacement warrants to purchase shares of series seed preferred stock and stock options to acquire Replimune Group, Inc. capital stock on a one-for-one basis. These transactions are collectively referred to as the reorganization. Upon completion of the reorganization, the historical consolidated financial statements of Replimune UK became the historical consolidated financial statements of Replimune Group, Inc. because the reorganization was accounted for similar to a reorganization of entities under common control due to the high degree of common ownership of Replimune UK and Replimune Group, Inc. and lack of economic substance to the transaction. The Company concluded that the reorganization resulted in no change in the material rights and preferences of each respective class of equity interests and no change in the fair value of each respective class of equity interests before and after the reorganization. On December 8, 2017, Replimune UK transferred all outstanding shares of its wholly owned subsidiary, Replimune US to Replimune Group, Inc. Replimune Group. Inc., a Delaware corporation, is the sole shareholder of Replimune UK, Replimune US and Replimune Securities Corporation, a Massachusetts corporation that was incorporated in November 2017.

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to secure additional capital to fund operations. Product candidates currently under development will require significant additional research and development efforts, including preclinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance and reporting capabilities. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

Forward stock split

On July 9, 2018, the Company effected a 1-for-9.94688 forward stock split of its issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios for each series of the Company's Preferred Stock (see Note 8). Accordingly, all share and per share amounts for all periods presented in the accompanying consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this forward stock split and adjustment of the preferred stock conversion ratios. Further, on July 9, 2018, the Company's authorized shares of common stock were increased to 27,314,288. Accordingly, the authorized shares of common

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

1. Nature of the business (Continued)

stock presented in the accompanying consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect the newly authorized shares of common stock.

Initial public offering

On July 24, 2018, the Company completed an initial public offering ("IPO") of its common stock and issued and sold 6,700,000 shares of common stock at a public offering price of $15.00 per share, resulting in net proceeds of $93,465 after deducting underwriting discounts and commissions but before deducting offering costs of $2,157.

Upon closing of the IPO, the Company's outstanding convertible preferred stock automatically converted into shares of common stock (see Note 8). Upon conversion of the convertible preferred stock, the Company reclassified the carrying value of the convertible preferred stock to common stock and additional paid-in capital. The warrant to purchase shares of the Company's series seed convertible preferred stock was converted into a warrant to purchase shares of the Company's common stock upon the closing of the IPO. As a result, the warrant liability was remeasured a final time on the closing date of the IPO and reclassified to stockholders' equity (deficit). Additionally, the Company repurchased 26,258 shares of class A common stock at a price equal to its par value upon the closing of the IPO.

On July 30, 2018, the Company issued and sold an additional 707,936 shares of its common stock at the IPO price of $15.00 per share pursuant to the underwriters' partial exercise of their option to purchase additional shares of common stock, resulting in additional net proceeds of $9,876 after deducting discounts and commissions and other offering expenses.

Also, in connection with the completion of its IPO on July 24, 2018, the Company filed an amended and restated certificate of incorporation with the Secretary of State of the State of Delaware to authorize the issuance of up to 150,000,000 shares of common stock, par value $0.001 per share, and 10,000,000 shares of undesignated preferred stock, par value $0.001 per share.

Basis of presentation

The accompanying consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the ordinary course of business. The Company has incurred recurring losses since its inception, including net losses of $52,625, $30,834 and $19,702 for the years ended March 31, 2020, 2019 and 2018, respectively. In addition, as of March 31, 2020, the Company had an accumulated deficit of $112,298. The Company expects to continue to generate operating losses for the foreseeable future. As of June 3, 2020, the issuance date of these consolidated financial statements, the Company expects that its cash and cash equivalents and short-term investments will be sufficient to fund its operating expenses and capital expenditure requirements through at least 12 months from the issuance of the consolidated financial statements. The future viability of the Company beyond that point is dependent on its ability to raise additional capital to finance its operations.

If the Company is unable to obtain funding it could be forced to delay, reduce or eliminate some or all of its research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect its business prospects, or it may be unable to continue operations. Although management continues to pursue these plans, there is no assurance that the Company will be

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

1. Nature of the business (Continued)

successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all.

Impact of the COVID-19 coronavirus

In December 2019, a novel strain of coronavirus, which causes the disease known as COVID-19, was reported to have surfaced in Wuhan, China. Since then, COVID-19 coronavirus has spread globally. In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic and the U.S. government imposed travel restrictions on travel between the United States, Europe and certain other countries. The impact of this pandemic has been, and will likely continue to be, extensive in many aspects of society, which has resulted, and will likely continue to result, in significant disruptions to the global economy as well as businesses and capital markets around the world.

In response to public health directives and orders and to help minimize the risk of the virus to employees, the Company has taken precautionary measures, including implementing work-from-home policies for certain employees. The impact of the virus, including work-from-home policies, may negatively impact productivity, disrupt the Company's business, and delay its preclinical research and clinical trial activities and its development program timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on the Company's ability to conduct its business in the ordinary course. Other impacts to the Company's business may include temporary closures of its suppliers and disruptions or restrictions on its employees' ability to travel. Any prolonged material disruption to the Company's employees or suppliers could adversely impact the Company's preclinical research and clinical trial activities, financial condition and results of operations, including its ability to obtain financing.

2. Summary of significant accounting policies

Principles of consolidation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP, and include the accounts of the Company and its wholly owned subsidiaries, Replimune UK, Replimune US and Replimune Securities Corporation, after elimination of all intercompany accounts and transactions. The consolidated financial statements reflect the capital as if Replimune Group, Inc. had been in existence for all periods presented.

Use of estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the accrual for research and development expenses and the valuation of common stock and stock-based awards. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances.

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

2. Summary of significant accounting policies (Continued)

The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition, including, expenses, research and development costs and employee-related amounts, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain it or treat COVID-19. We have made estimates of the impact of COVID-19 within our financial statements and there may be changes to those estimates in future periods.

Estimates are periodically reviewed in light of reasonable changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from those estimates or assumptions.

Foreign currency and currency translation

The functional currency for the Company's wholly owned foreign subsidiary, Replimune UK, is the British pound. Assets and liabilities of Replimune UK are translated into United States dollars at the exchange rate in effect on the balance sheet date. Revenues and expenses are translated at the average exchange rate in effect during the period. Unrealized translation gains and losses are recorded as a cumulative translation adjustment, which is included in the consolidated statements of convertible preferred stock and stockholders' equity (deficit) as a component of accumulated other comprehensive loss. Adjustments that arise from exchange rate changes on transactions denominated in a currency other than the local currency are included in other income (expense), net in the consolidated statements of operations as incurred.

Concentrations of credit risk and of significant suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents as well as short-term investments. The Company deposits its cash in financial institutions in amounts that may exceed federally insured limits, and has not experienced any losses on such accounts and does not believe it is exposed to any unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

The Company relies, and expects to continue to rely, on a small number of vendors to manufacture supplies and raw materials for its development programs. These programs could be adversely affected by a significant interruption in these manufacturing services or the availability of raw materials.

Cash and cash equivalents

The Company considers all highly liquid investments with original maturities of three months or less at date of purchase to be cash equivalents. Cash equivalents consisted of money market funds at March 31, 2020. Cash equivalents consisted of money market funds, U.S. Treasury bonds, and U.S. Government Agency Bonds at March 31, 2019. As of March 31, 2020 and 2019, cash equivalents totaled $36,712 and $10,664, respectively.

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

2. Summary of significant accounting policies (Continued)

Restricted cash

The Company maintains certain minimum balances in segregated bank accounts in connection with a letter of credit for the benefit of the landlords in connection with an operating lease. As of March 31, 2020 and 2019, restricted cash consisted of $1,636 and $1,186, respectively, held for the benefit of the landlords in connection with a financing lease and an operating lease. These amounts have been classified as non-current assets on the Company's consolidated balance sheets.

Short-term investments

The Company's short-term debt security investments are classified as available-for-sale and are carried at fair value, with the unrealized gains and losses reported as a component of accumulated other comprehensive income (loss) in stockholders' equity (deficit). Realized gains and losses and declines in value determined to be other than temporary are based on the specific identification method and are included as a component of other income (expense), net in the consolidated statements of operations.

The Company evaluates its short-term debt security investments with unrealized losses for other-than-temporary impairment. When assessing short-term debt security investments for other-than-temporary declines in value, the Company considers such factors as, among other things, how significant the decline in value is as a percentage of the original cost, how long the market value of the investment has been less than its original cost, the Company's ability and intent to retain the short-term debt security investment for a period of time sufficient to allow for any anticipated recovery in fair value and market conditions in general. If any adjustment to fair value reflects a decline in the value of the short-term debt security investment that the Company considers to be "other than temporary," the Company reduces the short-term debt security investment to fair value through a charge to the consolidated statements of operations. No such adjustments were necessary during the periods presented.

The Company's short-term debt security investments as of March 31, 2020 and 2019 had maturities of less than one year.

Deferred offering costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are recorded in stockholders' equity (deficit) as a reduction of proceeds generated as a result of the offering. Should an in-process equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the consolidated statements of operations. As of March 31, 2019, the Company recorded $2,157 of deferred offering costs in stockholders' equity (deficit) as a reduction of proceeds generated as a result of the IPO. The Company did not record any deferred offering costs as of March 31, 2020.

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

2. Summary of significant accounting policies (Continued)

Property, plant and equipment

Property, plant and equipment are stated at cost, less accumulated depreciation and amortization. Depreciation and amortization expense is recognized using the straight-line method over the estimated useful lives of the respective assets as follows:

	Estimated Useful life
Office equipment	5 years
Computer equipment	3 years
Plant, plant and laboratory equipment	5 years
Leasehold improvements	Lesser of lease term or 10 years

Costs for capital assets not yet placed into service are capitalized as construction-in-progress and depreciated in accordance with the above guidelines once placed into service. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is included in loss from operations. Expenditures for repairs and maintenance are charged to expense as incurred.

Impairment of long-lived assets

Long-lived assets consist of property, plant and equipment. Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset group for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset group to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset group are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset group over its fair value, determined based on discounted cash flows. To date, the Company has not recorded any impairment losses on long-lived assets.

Fair value measurements

Certain assets and liabilities of the Company are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

2. Summary of significant accounting policies (Continued)

levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company's short-term investments, cash equivalents and warrant liability are carried at fair value, determined according to the fair value hierarchy described above (see Note 3). The carrying values of research and development incentives receivable, other current assets, accounts payable and accrued expenses and other current liabilities approximate their fair values due to the short-term nature of these assets and liabilities. The carrying value of the Company's outstanding loan agreement with Hercules approximates its fair value at March 31, 2020 because the debt bears interest at a variable market rate and the Company's credit risk has not materially changed since the inception of the agreement.

Warrant liability

Upon the closing of the IPO, the warrants to purchase shares of the Company's series seed convertible preferred stock were converted into warrants to purchase shares of the Company's common stock. As a result, the warrant liability was remeasured a final time on the closing date of the IPO and reclassified to stockholders' equity (deficit).

Prior to the IPO, the Company classified warrants to purchase shares of series seed preferred stock (see Note 8) as a liability on its consolidated balance sheets as these warrants to purchase shares of series seed preferred stock were free-standing financial instruments that could require the Company to transfer assets upon exercise. The warrant liability was initially recorded at fair value upon the date of the warrants' issuance and was subsequently remeasured to fair value at each reporting date. Changes in the fair value of the warrant liability were recognized as a component of total other income (expense), net in the consolidated statements of operations.

The Company utilized the Black-Scholes option-pricing model, which incorporated assumptions and estimates, to value the warrant liability. The Company assessed these assumptions and estimates on a quarterly basis as additional information impacting assumptions was obtained. Estimates and assumptions impacting the fair value measurement included the expected stock price volatility, the expected term of the warrant, the risk-free interest rate for a period that approximated the expected term of the warrant, and the Company's expected dividend yield (see Note 3).

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

2. Summary of significant accounting policies (Continued)

Debt issuance costs

Debt issuance costs consist of payments made to secure commitments under certain debt financing arrangements. These amounts are recognized as interest expense over the period of the financing arrangement using the effective interest method. If the financing arrangement is canceled or forfeited, or if the utility of the arrangement to the Company is otherwise compromised, these costs are recognized as interest expense immediately. The Company's consolidated financial statements present debt issuance costs related to a recognized debt liability as a direct reduction from the carrying amount of that debt liability.

Segment information

The Company manages its operations as a single operating segment for the purposes of assessing performance and making operating decisions. The Company's current focus is on developing oncolytic immunotherapies for the treatment of cancer.

Research and development costs

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities, including salaries, stock-based compensation and benefits, facilities costs and laboratory supplies, depreciation and external costs of outside vendors engaged to conduct preclinical development, clinical development activities and clinical trials as well as to manufacture clinical trial materials. Non-refundable prepayments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. Such amounts are recognized as an expense as the goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered or the services rendered. Upfront payments for materials and supplies acquired for particular research and development activities that have no alternative future use in other research and development projects or otherwise, and therefore have no separate economic value, are expensed as research and development costs at the time the costs are incurred.

Research contract costs and accruals

The Company has entered into various research and development-related contracts with companies both inside and outside of the United States. These agreements are generally cancelable, and related costs are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies or clinical trials, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

2. Summary of significant accounting policies (Continued)

Patent costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses.

Stock-based compensation

The Company measures all stock-based awards granted to employees, consultants, and non-employees and directors based on the fair value on the date of the grant and recognizes compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model, which requires inputs based on certain subjective assumptions, including the expected stock price volatility, the expected term of the option, the risk-free interest rate for a period that approximates the expected term of the option, and the Company's expected dividend yield (see Note 9). Forfeitures are accounted for as they occur. To date, the Company has issued stock-based awards with only service-based vesting conditions and records the expense for these awards using the straight-line method.

The Company classifies stock-based compensation expense in its consolidated statements of operations in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

Research and development incentives and receivable

The Company, through its subsidiary in the United Kingdom, receives reimbursements of certain research and development expenditures as part of a United Kingdom government's research and development tax reliefs program. Under the program, a percentage of qualifying research and development expenses incurred by the Company's subsidiary in the United Kingdom are reimbursed up to 14.5%.

Management has assessed the Company's research and development activities and expenditures to determine which activities and expenditures are likely to be eligible under the research and development incentive program described above. At each period end, management estimates the reimbursement available to the Company based on available information at the time.

The Company recognizes income from the research and development incentives when the relevant expenditure has been incurred, the associated conditions have been satisfied and there is reasonable assurance that the reimbursement will be received. The Company records these research and development incentives as other income. The research and development incentives receivable represents an amount due in connection with the above program. The Company recorded other income from research and development incentives of $3,084, $2,528 and $2,267 during the years ended March 31, 2020, 2019 and 2018, respectively, in the consolidated statements of operations and a research and development incentives receivable of $2,962 and $2,474 as of March 31, 2020 and 2019, respectively, on the consolidated balance sheets.

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

2. Summary of significant accounting policies (Continued)

Comprehensive loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity (deficit) that result from transactions and economic events other than those with stockholders. For the year ended March 31, 2020, comprehensive loss included $(236) of foreign currency translation adjustments and $309 of unrealized gains on short-term investments, net of tax. For the year ended March 31, 2019, comprehensive loss included $(897) of foreign currency translation adjustments and $80 of unrealized gains on short-term investments, net of tax. For the year ended March 31, 2018, comprehensive loss included $2,376 of foreign currency translation adjustments and $(65) of unrealized losses on short-term investments, net of tax.

Income taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in the Company's tax returns. Deferred tax assets and liabilities are determined on the basis of the differences between the consolidated financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes recognized in the consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the consolidated financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

Net income (loss) per share

The Company follows the two-class method when computing net income (loss) per share as the Company has issued shares that meet the definition of participating securities. The two-class method determines net income (loss) per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed.

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

2. Summary of significant accounting policies (Continued)

Basic net income (loss) per share attributable to common stockholders is computed by dividing the net income (loss) attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period. Diluted net income (loss) attributable to common stockholders is computed by adjusting net income (loss) attributable to common stockholders to reallocate undistributed earnings based on the potential impact of dilutive securities. Diluted net income (loss) per share attributable to common stockholders is computed by dividing the diluted net income (loss) attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period, including potential dilutive common shares assuming the dilutive effect of common stock equivalents.

The Company's convertible preferred stock contractually entitled the holders of such shares to participate in dividends but contractually did not require the holders of such shares to participate in losses of the Company. Accordingly, in periods in which the Company reported a net loss, such losses were not allocated to such participating securities. In periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

Recently adopted accounting pronouncements

In June 2018, the FASB issued Accounting Standards Updates ("ASU") No. 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"). ASU 2018-17 expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. ASU 2018-17 also clarifies that Topic 718 does not apply to share-based payments used to effectively provide (1) financing to the issuer or (2) awards granted in conjunction with selling goods or services to customers as part of a contract accounted for under Revenue from Contracts with Customers (Topic 606). The guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted. The Company adopted ASU 2018-17 on April 1, 2019. The adoption of ASU 2018-17 did not have a material impact on the Company's consolidated financial statements.

In July 2017, the FASB issued ASU No. 2017-11, Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815) I. Accounting for Certain Financial Instruments with Down Round Features II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception ("ASU 2017-11"). Part I applies to entities that issue financial instruments such as warrants, convertible debt or convertible preferred stock that contain down-round features. Part II replaces the indefinite deferral for certain mandatorily redeemable noncontrolling interests and mandatorily redeemable financial instruments of nonpublic entities contained within Accounting Standards Codification ("ASC") Topic 480 with a scope exception and does not impact the accounting for these mandatorily redeemable instruments. ASU 2017-11 is required to be adopted for annual periods beginning after December 15, 2018, including interim periods within those fiscal years. The Company adopted ASU 2017-11 on April 1, 2019. The adoption of ASU 2017-11 did not have a material impact on the Company's consolidated financial statements.

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

2. Summary of significant accounting policies (Continued)

In February 2016, the FASB issued ASU No. 2016-02 *("ASU 2016-02"), Leases (Topic 842),* which supersedes FASB Topic 840, *Leases (Topic 840)* and provides principles for the recognition, measurement, presentation and disclosure of leases for both lessees and lessors. The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of classification. Leases with a term of 12 months or less will be accounted for similar to existing guidance for operating leases. In January 2018, the FASB issued ASU 2018-01, *Leases (Topic 842) Land Easement Practical Expedient for Transition to Topic 842,* which amends ASU 2016-02 to provide entities an optional transition practical expedient to not evaluate under Topic 842 existing or expired land easements that were not previously accounted for as leases under the current leases guidance in Topic 842. An entity that elects this practical expedient should evaluate new or modified land easements under Topic 842 beginning at the date that the entity adopts Topic 842. In July 2018, the FASB also issued ASU 2018-11, *Leases (Topic 842): Targeted Improvements*, which provides an optional transition method that allows entities to elect to apply the standard prospectively at its effective date, versus recasting the prior periods presented.

The Company adopted ASU 2016-02, as amended, on April 1, 2019, which supersedes the current leasing guidance and upon adoption, requires lessees to recognize right-of-use assets and lease liabilities on the balance sheet for all leases with terms longer than 12 months. Leases are classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. Upon the adoption of the guidance, operating leases are capitalized on the balance sheet at the present value of lease payments. The balance sheet amount recorded for existing leases at the date of adoption of ASU 2016-02 was calculated using the applicable incremental borrowing rate at the date of adoption.

The Company elected the available package of practical expedients, which allows the Company to not reassess previous accounting conclusions around whether arrangements are or contain leases, the classification of leases, and the treatment of initial direct costs. The Company also made an accounting policy election to utilize the short-term lease exemption, whereby leases with a term of 12 months or less will not follow the recognition and measurement requirements of the new standard. Upon adoption, the Company recognized total right-of-use assets of $789, with corresponding liabilities of $837 on the consolidated balance sheets. Additionally, the Company derecognized $11,514 of construction in progress assets and $6,561 of financing obligations and recorded long term prepaid rent of $5,006 on the consolidated balance sheet (see Note 12).

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

2. Summary of significant accounting policies (Continued)

The following table summarizes the financial impact on the Company's consolidated balance sheet upon the adoption of ASU 2016-02 and the cumulative effect adjustment on April 1, 2019:

	March 31, 2019	Adjustments	April 1, 2019
Property, plant, and equipment, net	$ 12,159	$ (11,514)	$ 645
Right-to-use asset	$ —	$ 789	$ 789
Long term prepaid rent	$ —	$ 5,006	$ 5,006
Lease liabilities, current	$ —	$ 388	$ 388
Lease liabilities, non-current	$ —	$ 449	$ 449
Accrued expenses	$ 2,801	$ (24)	$ 2,777
Deferred rent, net of current portion	$ 24	$ (24)	$ —
Financing obligation	$ 6,561	$ (6,561)	$ —
Accumulated deficit	$ (59,766)	$ 93	$ (59,673)

Recently issued accounting pronouncements

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820), Disclosure Framework- Changes to the Disclosure Requirements for Fair Value Measurement* ("ASU 2018-13"). The amendments in this ASU require certain existing disclosure requirements in Topic 820 to be modified or removed, and certain new disclosure requirements to be added to the Topic. In addition, this ASU allows entities to exercise more discretion when considering fair value measurement disclosures. ASU 2018-13 will be effective for the Company beginning April 1, 2020 with early adoption permitted. The adoption of ASU 2018-13 is not expected to have a material impact on the Company's consolidated financial statements.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments- Credit Losses (Topic 326).* The standard changes how entities will measure credit losses for most financial assets and certain other instruments that are not measured at fair value through net income. Financial assets measured at amortized cost will be presented at the net amount expected to be collected by using an allowance for credit losses. In April 2019, the FASB issued ASU No. 2019-04, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments*, which clarifies and corrects certain unintended applications of the guidance contained in each of the amended Topics. Additionally, in May 2019, the FASB issued ASU No. 2019-05, *Financial Instruments—Credit Losses (Topic 326)*, which provides an option to irrevocably elect to measure certain individual financial assets at fair value instead of amortized cost. The standard is effective for fiscal years and interim periods beginning after December 15, 2019. Early adoption is permitted for all periods beginning after December 15, 2018. The adoption of ASU 2018-13 is not expected to have a material impact on the Company's consolidated financial statements.

In November 2018, the FASB issued ASU No. 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606* ("ASU2018-18"), which clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer in the context of a unit of account. In those situations, all the guidance in Topic 606 should be applied, including recognition,

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

2. Summary of significant accounting policies (Continued)

measurement, presentation, and disclosure requirements. The standard adds unit-of-account guidance in Topic 808 to align with the guidance in Topic 606 (that is, a distinct good or service) when an entity is assessing whether the collaborative arrangement or a part of the arrangement is within the scope of Topic 606, and requires that in a transaction with a collaborative arrangement participant that is not directly related to sales to third parties, presenting the transaction together with revenue recognized under Topic 606 is precluded if the collaborative arrangement participant is not a customer. The standard is effective for interim and annual periods beginning after December 15, 2019, with early adoption permitted, including adoption in any interim period for public business entities for periods in which financial statements have not been issued. Amendments in the standard should be applied retrospectively to the date of initial application of Topic 606, but entities may elect to apply the amendments in this Update retrospectively either to all contracts or only to contracts that are not completed at the date of initial application of Topic 606, and should disclose the election. An entity may also elect to apply the practical expedient for contract modifications that is permitted for entities using the modified retrospective transition method in Topic 606. The adoption of ASU 2018-13 is not expected to have a material impact on the Company's consolidated financial statements.

3. Fair value of financial assets and liabilities

The following tables present information about the Company's financial assets and liabilities measured at fair value on a recurring basis:

	Fair Value Measurements as of March 31, 2020 Using:			
	Level 1	Level 2	Level 3	Total
Assets				
Money market funds	$ —	$ 36,712	$ —	$ 36,712
Commercial paper	—	21,884	—	21,884
US Treasury bonds	—	35,810	—	35,810
US Government Agency bonds	—	15,295	—	15,295
Corporate debt securities	—	36,066	—	36,066
	$ —	$ 145,767	$ —	$ 145,767

	Fair Value Measurements as of March 31, 2019 Using:			
	Level 1	Level 2	Level 3	Total
Assets				
Money market funds	$ —	$ 2,676	$ —	$ 2,676
Commercial paper	—	46,687	—	46,687
US Government Agency bonds	—	20,884	—	20,884
US Treasury bonds	—	41,057	—	41,057
Corporate debt securities	—	8,467	—	8,467
	$ —	$ 119,771	$ —	$ 119,771

During the years ended March 31, 2020 and 2019, there were no transfers between levels.

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

3. Fair value of financial assets and liabilities (Continued)

Valuation of cash equivalents and short-term investments

Money market funds, commercial paper, U.S. Treasury bonds, U.S. Government Agency bonds and corporate debt securities were valued by the Company using quoted prices in active markets for similar securities, which represent a Level 2 measurement within the fair value hierarchy. Cash equivalents consisted of money market funds at March 31, 2020. Cash equivalents consisted of money market funds, U.S. Treasury bonds, and U.S. Government Agency Bonds at March 31, 2019.

Valuation of warrant liability

The warrant liability is related to the warrants to purchase shares of series seed preferred stock (see Note 8). The fair value of the warrant liability was determined based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. Upon the closing of the IPO in July 2018, the warrant to purchase shares of the Company's series seed convertible preferred stock was converted into a warrant to purchase shares of the Company's common stock. As a result, the warrant liability was remeasured a final time on the closing date of the IPO and reclassified to stockholders' equity (deficit).

The Company used the Black-Scholes option-pricing model, which incorporated assumptions and estimates, to value the warrant liability. Key estimates and assumptions impacting the fair value measurement include (i) the expected term of the warrants, (ii) the risk-free interest rate, (iii) the expected dividend yield, (iv) expected volatility of the price of the underlying series seed preferred stock and (v) the fair value of the series seed preferred stock on the valuation date. The Company estimated the fair value per share of the underlying series seed preferred stock based, in part, on the results of third-party valuations and additional factors deemed relevant. The risk-free interest rate was determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the warrants. The Company estimated a 0% expected dividend yield based on the fact that the Company has never paid or declared dividends and does not intend to do so in the foreseeable future. Prior to July 2018, the Company was a private company and accordingly, lacked company-specific historical and implied volatility information of its stock, the expected stock volatility was based on the historical volatility of publicly traded peer companies for a term equal to the remaining expected term of the warrants.

Based on the terms and conditions of the warrant, upon closing of the Company's IPO in July 2018, the warrant to purchase shares of the Company's series seed convertible preferred stock was converted into a warrant to purchase shares of the Company's common stock. On that date, the Company remeasured the warrant liability to fair value and reclassified the total carrying value to additional paid-in capital. The Company performed the final remeasurement of the warrant liability using the IPO price of $15.00 per share and recorded the change in fair value as a component of total other income (expense), net in the consolidated statement of operations.

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

3. Fair value of financial assets and liabilities (Continued)

The following assumptions were used to measure the fair market value of the warrant liability upon the conversion date:

	Year Ended March 31,2019
Risk-free interest rate	2.81%
Expected term (in years)	7.2
Expected volatility	64.4%
Expected dividend yield	0%
Fair value of series seed preferred stock	$ 15.00

The following table presents a roll forward of the warrant liability:

	Warrant Liability
Balance at March 31, 2018	$ 1,642
Change in fair value	5,452
Conversion of convertible preferred stock warrant into common stock warrant	(7,094)
Balance at March 31, 2019	$ —

4. Short-term investments

Short-term investments by investment type consisted of the following:

	March 31, 2020			
	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
Commercial paper	$ 21,818	$ 66	$ —	$ 21,884
US Government agency bonds	15,217	78	—	15,295
US Treasury bonds	35,590	220	—	35,810
Corporate debt securities	36,107	24	(65)	36,066
	$ 108,732	$ 388	$ (65)	$ 109,055

	March 31, 2019			
	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
Commercial paper	$ 46,687	$ 2	$ (2)	$ 46,687
US Government agency bonds	15,889	4	—	15,893
US Treasury bonds	38,047	13	—	38,060
Corporate debt securities	8,469	—	(2)	8,467
	$ 109,092	$ 19	$ (4)	$ 109,107

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

5. Property, plant and equipment, net

Property, plant and equipment, net consisted of the following:

	March 31,	
	2020	2019
Construction in progress	$ 1,217	$ 124
Plant and laboratory equipment	3,669	584
Leasehold improvements	532	154
Computer equipment	1,658	138
Office equipment	721	49
Build-to-suit lease asset	—	11,514
	7,797	12,563
Less: Accumulated depreciation and amortization	(937)	(404)
	$ 6,860	$ 12,159

Depreciation and amortization expense was $533, $148 and $109 for the years ended March 31, 2020, 2019 and 2018, respectively, and recorded within research and development and general and administrative expenses in the consolidated statement of operations.

Build-to-suit lease asset, as of March 31, 2019, included $11,514 capitalized in connection with the Company's build-to-suit lease accounting. Upon transition to ASC 842, the Company determined that it did not control the build-to-suit lease asset and the arrangement has been accounted for under ASC 842 guidance. Upon the adoption of ASC 842, the Company derecognized $11,514 of construction in progress and $6,561 of financing obligations and recorded long term prepaid rent of $5,006 on the consolidated balance sheet (see Note 12).

6. Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consisted of the following:

	March 31,	
	2020	2019
Accrued researched and development costs	$ 2,009	$ 530
Accrued compensation and benefits costs	2,065	1,510
Accrued professional fees	779	464
Deferred rent	—	24
Other	303	273
	$ 5,156	$ 2,801

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

7. Long-term debt

Long-term debt consisted of the following:

	March 31, 2020
Principal amount of long-term debt	$ 10,000
Unamortized debt discount	(199)
Long-term debt, net of discount	$ 9,801

Hercules Loan Agreement

On August 8, 2019, (the "Closing Date") the Company and certain of its affiliates entered into a Loan and Security Agreement (the "Hercules Loan Agreement") with Hercules Capital, Inc. ("Hercules") pursuant to which Hercules agreed to make available to the Company a secured term loan facility in the amount of $30,000 (the "Term Loan Facility"), subject to certain terms and conditions. The Company borrowed $10,000 under the Hercules Loan Agreement in one advance as a single tranche Term Loan on the Closing Date upon which the Company paid a $225 facility charge and incurred $130 in additional closing and legal fees. The Company may borrow the unused $20,000 available under the Term Loan Facility in two separate advances. The second advance of up to $10,000 may be borrowed between January 1, 2020 and December 15, 2020 and the third advance of up to $10,000 may be borrowed between July 1, 2020 and June 30, 2021.

Advances under the Term Loan Facility bear interest at a rate per annum equal to the greater of either (i) the prime rate as reported in The Wall Street Journal plus 2.75%, or (ii) 8.75%. The Hercules Loan Agreement includes covenants, limitations, and events of default customary for similar facilities. The term of the Hercules Loan Agreement is four years, ending August 1, 2023.

Interest is payable on a monthly basis until March 1, 2022 (the "Amortization Date"). After the Amortization Date, payments shall consist of equal monthly installments of principal and interest payable until the secured obligations are repaid in full.

At any time the Company may prepay the principal of any advance pursuant to the terms of the Term Loan Facility subject to a prepayment charge equal to: 3.0%, if such advance is prepaid within the first twelve months following the Closing Date, 2.0%, if such advance is prepaid after twelve months but prior to twenty four months following the Closing Date, and 1.0%, if such advance is prepaid anytime thereafter. The Company will also pay a charge equal to the product of 4.95% and the aggregate amount of any advance made pursuant to the terms of the Term Loan Facility.

The Term Loan Facility is secured by substantially all of the Company's assets, but excluding its intellectual property, and subject to certain exceptions and exclusions.

The Hercules Loan Agreement contains customary covenants for transactions of this type and other covenants agreed to by the parties, including, among others, (i) the provision of delivery of annual and quarterly financial statements and insurance policies and restrictions on incurring debt, granting liens, making acquisitions, making loans, paying dividends, dissolving, and entering into leases and asset sales. The Hercules Loan Agreement also provides for customary events of default, including,

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

7. Long-term debt (Continued)

among others, events of default relating to failure to make payment, bankruptcy, breach of covenants, breaches of representations and warranties, change of control, judgment and material adverse effects.

In connection with entering into the Hercules Loan Agreement the Company paid Hercules $355 of upfront fees, including closing costs and legal fees associated with entering into the agreement, which were recorded as a debt discount. The debt discount is reflected as a reduction of the carrying value of long-term debt on the Company's consolidated balance sheet and is being amortized to interest expense over the term of the loan using the effective interest method.

The Company recognized aggregate interest expense under the Hercules Loan Agreement of $734 during the year ended March 31, 2020, which included non-cash interest expense of $60 and $96 related to the accretion of the debt discount and the final payment. As of March 31, 2020, the unamortized debt discount was $199. The Company's annual effective interest rate of the Hercules Loan Agreement was approximately 10.1% for the period from August 8, 2019 to March 31, 2020.

There were no principal payments due or paid under the Hercules Loan Agreement during the year ended March 31, 2020.

Future payments of long-term debt, including interest, as of March 31, 2020 are as follows (fiscal years):

Future long-term debt payments:	
2021	$ —
2022	527
2023	6,558
2024	2,915
Total debt payments	$ 10,000

The table of future payments of long-term debt excludes the end of term charge of $495 which is due upon the maturity of the loan.

8. Stockholders' Equity

Common stock

As of March 31, 2020 and 2019, the Company's certificate of incorporation, as amended and restated, authorized the Company to issue up to 150,000,000 shares of common stock, par value $0.00l per share.

As of March 31, 2020 and 2019, the Company had reserved 10,449,033 and 6,873,744 shares of common stock for the exercise of outstanding stock options, the number of shares remaining available for grant under the Company's 2018 Omnibus Incentive Compensation Plan and the Company's Employee Stock Purchase Plan (see Note 9) and the exercise of the outstanding warrants to purchase shares of common, respectively.

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

8. Stockholders' Equity (Continued)

Undesignated preferred stock

As of March 31, 2020, the Company's certificate of incorporation, as amended and restated, authorized the Company to issue up to 10,000,000 shares of undesignated preferred stock, par value $0.001 per share. There were no undesignated preferred shares issued or outstanding as of March 31, 2020.

Convertible preferred stock

The Company has issued series seed convertible preferred stock (the "series seed preferred stock"), series A convertible preferred stock (the "series A preferred stock") and series B convertible preferred stock (the "series B preferred stock"). The series seed preferred stock, series A preferred stock and series B preferred stock are collectively referred to as the "preferred stock." In connection with the closing of the IPO, the preferred stock converted into 19,157,360 shares of common stock on a 1:9.94688 basis. There was no preferred stock outstanding as of March 31, 2020 and 2019.

Preferred stock warrants

In connection with the issuance of the series seed preferred stock, the Company issued to the holders of the series seed preferred stock warrants for the purchase of 50,000 shares of series seed preferred stock, which became fully vested and exercisable in the year of issuance. The warrants to purchase shares of series seed preferred stock were issued at an exercise price of $10.00 per share and expire on the earlier of September 16, 2025 or a qualified change of control event.

The issuance date fair value of the warrants to purchase shares of series seed preferred stock was $391 and was recorded as a liability with a corresponding reduction in the carrying value of the series seed preferred stock. The Company did not recognize any losses for the change in fair value of warrant liability within total other income (expense), net in the consolidated statements of operations for the years ended March 31, 2020, related to the change in fair value of the warrant liability. The Company recognized a loss of $(5,452) and $(972), in change in fair value of warrant liability within total other income (expense), net in the consolidated statements of operations for the year ended March 31, 2019 and 2018, respectively, related to the change in fair value of the warrant liability.

Upon the closing of the Company's IPO in July 2018, all outstanding convertible preferred stock was converted into common stock and the series seed preferred stock warrants became exercisable for 497,344 shares of common stock instead of series seed preferred stock. As a result, the warrant liability was remeasured a final time on the closing date of the IPO and reclassified to stockholders' equity.

ATM program

In August 2019, the Company entered into a Sales Agreement (the "Sales Agreement") with SVB Leerink LLC (the "Agent"), pursuant to which the Company may sell, from time to time, at its option, up to an aggregate amount of $75,000 of shares of the Company's common stock, $0.001 par value per share (the "Shares"), through the Agent, as the Company's sales agent.

Any Shares to be offered and sold under the Sales Agreement will be issued and sold (i) by methods deemed to be an "at the market offering" ("ATM"), as defined in Rule 415(a)(4) promulgated

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

8. Stockholders' Equity (Continued)

under the Securities Act of 1933, as amended or in negotiated transactions, if authorized by the Company, and (ii) pursuant to, and only upon the effectiveness of, a registration statement on Form S-3 filed by the Company with the Securities and Exchange Commission on August 8, 2019 for an offering of up to $250,000 of various securities, including shares of the Company's common stock, preferred stock, debt securities, warrants and/or units for sale to the public in one or more public offerings.

Subject to the terms of the Sales Agreement, the Agent will use commercially reasonable efforts to sell the Shares from time to time, based upon the Company's instructions (including any price, time or size limits or other customary parameters or conditions the Company may impose). The Company will pay the Agent a commission of 3.0% of the gross proceeds from the sale of the Shares, if any. During the year ended March 31, 2020, the Company has issued and sold 287,559 shares of common stock for gross proceeds of $4,568 less offering fees of $137 for net proceeds of $4,431 under the ATM program.

Equity offerings

In November 2019, the Company entered into an Underwriting Agreement (the "Underwriting Agreement") with J.P. Morgan Securities LLC and SVB Leerink LLC, as representatives of the several underwriters named therein (the "Underwriters"), relating to the issuance and sale of an aggregate of (a) 3,678,031 shares of the Company's common stock (the "Shares"), and (b) pre-funded warrants to purchase 2,200,000 shares of the Company's common stock (the "Pre-Funded Warrants") to the Underwriters (the "Offering"). The Shares were sold to the purchasers at the public offering price of $13.61 per share. The Pre-Funded Warrants were sold at a public offering price of $13.6099 per Pre-Funded Warrant, which represents the per share public offering price for the Company's common stock less a $0.0001 per share exercise price for each such Pre-Funded Warrant. Pursuant to the Underwriting Agreement, the Company also granted the Underwriters a 30-day option to purchase up to 881,704 additional shares of its common stock. In December 2019, the Underwriters partially exercised their purchase option and the Company issued and sold an additional 838,530 shares of its common stock. The Company received aggregate net proceeds of approximately $85,598 after deducting underwriting discounts, commissions and other offering expenses payable by the Company of approximately $5,814.

The Pre-Funded Warrants are exercisable at any time after the date of issuance. A holder of Pre-Funded Warrants may not exercise the Pre-Funded Warrant if the holder, together with its affiliates, would beneficially own more than 9.99% of the number of shares of the Company's common stock outstanding immediately after giving effect to such exercise. A holder of Pre-Funded Warrants may increase or decrease this percentage by providing at least 61 days' prior notice to the Company. As of March 31, 2020, none of the warrants had been exercised.

9. Stock-based compensation

2015 Enterprise Management Incentive Share Option Plan

The 2015 Enterprise Management Incentive Share Option Plan of Replimune UK (the "2015 Plan") provided for Replimune UK to grant incentive stock options, non-statutory stock options, stock awards, stock units, stock appreciation rights and other stock-based awards. Incentive stock options are

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

9. Stock-based compensation (Continued)

granted only to the Company's employees, including officers and directors who are also employees. Non-statutory stock options are granted to employees, members of the board of directors, outside advisors and consultants of the Company.

2017 Equity Compensation Plan

In July 2017, in conjunction with the Reorganization, the 2015 Plan was terminated, and all awards were cancelled with replacement awards issued under the 2017 Equity Compensation Plan (the "2017 Plan"). Subsequent to the Reorganization, no additional grants will be made under the 2015 Plan and any outstanding awards under the 2015 Plan will continue with their original terms. The Company concluded that the cancellation of the 2015 Plan and issuance of replacement awards under the 2017 Plan was a modification with no change in the material rights and preferences and therefore no recorded change in the fair value of each respective award.

The Company's 2017 Plan provides for the Company to grant incentive stock options or non-statutory stock options, stock awards, stock units, stock appreciation rights and other stock-based awards. Incentive stock options may be granted only to the Company's employees, including officers and directors who are also employees. Restricted stock awards and non-statutory stock options may be granted to employees, officers, members of the board of directors, advisors and consultants of the Company. The maximum number of common shares that may be issued under the 2017 Plan was 2,659,885 of which 0 remained available for future grants as of March 31, 2020. Shares with respect to which awards have expired, terminated, surrendered or cancelled under the 2017 Plan without having been fully exercised will be available for future awards under the 2017 Plan. In addition, shares of common stock that are tendered to the Company by a participant to exercise an award are added to the number of shares of common stock available for the grant of awards.

2018 Omnibus Incentive Compensation Plan

On July 9, 2018, the Company's board of directors adopted, and the Company's stockholders approved the 2018 Omnibus Incentive Compensation Plan (the "2018 Plan"), which became effective immediately prior to the effectiveness of the registration statement for the Company's initial public offering. The 2018 Plan provides for the issuance of incentive stock options, non-qualified stock options, stock awards, stock units, stock appreciation rights and other stock-based awards. The number of shares initially reserved for issuance under the 2018 Plan is 3,617,968 shares. If any options or stock appreciation rights, including outstanding options and stock appreciation rights granted under the 2017 Plan (up to 2,520,247 shares), terminate, expire, or are canceled, forfeited, exchanged, or surrendered without having been exercised, or if any stock awards, stock units or other stock-based awards, including outstanding awards granted under the 2017 Plan, are forfeited, terminated, or otherwise not paid in full in shares of common stock, the shares of the Company's common stock subject to such grants will be available for purposes of our 2018 Plan. On April 1, 2019, the number of shares reserved for issuance under the 2018 Plan automatically increased by 1,266,278 shares pursuant to the terms of the 2018 Plan. As of March 31, 2020, 2,122,012 shares remained available for future grants under the 2018 Plan.

The 2015 Plan, the 2017 Plan and the 2018 Plan was administered by the board of directors or, at the discretion of the board of directors, by a committee of the board of directors. However, the board

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

9. Stock-based compensation (Continued)

of directors shall administer and approve all grants made to non-employee directors. The exercise prices, vesting and other restrictions are determined at the discretion of the board of directors, except that the exercise price per share of incentive stock options may not be less than 100% of the fair market value of the common stock on the date of grant (or 110% of fair value in the case of an award granted to employees who hold more than 10% of the total combined voting power of all classes of stock at the time of grant) and the term of stock options may not be greater than five years for an incentive stock option granted to a 10% stockholder and greater than ten years for all other options granted. Stock options awarded under both plans expire ten years after the grant date, unless the board of directors sets a shorter term. Vesting periods for both plans are determined at the discretion of the board of directors. Incentive stock options granted to employees and non-statutory options granted to employees, officers, members of the board of directors, advisors, and consultants of the Company typically vest over four years.

Employee Stock Purchase Plan

On July 9, 2018, the Company's board of directors adopted and the Company's stockholders approved the Employee Stock Purchase Plan (the "ESPP"), which became effective immediately prior to the effectiveness of the registration statement for the Company's IPO. The total shares of common stock initially reserved for issuance under the ESPP is limited to 348,612 shares. In addition, as of the first trading day of each fiscal year during the term of the ESPP (excluding any extensions), an additional number of shares of the Company's common stock equal to 1% of the total number of shares outstanding on the last trading day in the immediately preceding fiscal year or 697,224 shares, whichever is less (or such lesser amount as determined by the Company's board of directors) will be added to the number of shares authorized under the ESPP. In accordance, on April 1, 2019, the number of shares reserved for issuance under the ESPP automatically increased by 316,569 shares, for a total of 665,181 shares reserved for the ESPP. If the total number of shares of common stock to be purchased pursuant to outstanding purchase rights on any particular date exceed the number of shares then available for issuance under the ESPP, then the plan administrator will allocate the available shares pro-rata and refund any excess payroll deductions or other contributions to participants.

Stock option valuation

The fair value of stock option grants is estimated using the Black-Scholes option-pricing model. The Company lacks company-specific historical and implied volatility information. Therefore, it estimated its expected stock volatility based on the historical volatility of a publicly traded set of peer companies. For options with service-based vesting conditions, the expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The expected term of stock options granted to non-employees is equal to the contractual term of the option award. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

9. Stock-based compensation (Continued)

The following table presents, on a weighted-average basis, the assumptions that the Company used to determine the grant-date fair value of stock options granted to employees and directors:

	Year Ended March 31,		
	2020	2019	2018
Risk-free interest rate	2.12%	2.81%	2.01%
Expected term (in years)	6.0	6.1	6.0
Expected volatility	71.4%	62.0%	75.0%
Expected dividend yield	0%	0%	0%

The following table presents the assumptions that the Company used to determine the grant-date fair value of stock options granted to a non-employee:

	Year Ended March 31, 2018
Risk-free interest rate	2.29%
Expected term (in years)	10.0
Expected volatility	75.0%
Expected dividend yield	0%

All outstanding non-employee options granted during the year ended March 31, 2018 have vested, and there were no options granted to non-employees during the year ended March 31, 2020 or 2019.

Stock options

The following table summarizes the Company's stock option activity:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding as of March 31, 2019	3,721,784	$ 7.14	8.61	$ 30,150
Granted	1,637,035	15.07	9.21	
Exercised	(207,673)	2.65		
Cancelled	(186,765)	11.48		
Outstanding as of March 31, 2020	4,964,381	$ 9.78	8.02	$ 15,344
Options exercisable as of March 31, 2019	1,278,330	$ 2.51	7.75	$ 16,249
Options exercisable as of March 31, 2020	2,117,721	$ 5.66	7.20	11,733

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock.

The weighted average grant-date fair value per share of stock options granted during the years ended March 31, 2020 and 2019 was $9.70 and $8.82, respectively. The total fair value of options vested

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

9. Stock-based compensation (Continued)

during the years ended March 31, 2020 and 2019 was $5,440 and $1,298, respectively. As of March 31, 2020, there were no outstanding unvested service-based stock options held by non-employees.

Stock-based compensation expense

Stock-based compensation expense was classified in the consolidated statements of operations as follows:

	Year Ended March 31,		
	2020	2019	2018
Research and development	$ 3,689	$ 1,488	$ 335
General and administrative	4,052	1,242	477
	$ 7,741	$ 2,730	$ 812

As of March 31, 2020, total unrecognized compensation cost related to the unvested stock-based awards was $18,732, which is expected to be recognized over a weighted average period of 2.56 years.

10. Net loss per share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows:

	Year Ended March 31,		
	2020	2019	2018
Numerator:			
Net loss attributable to common stockholders	$ (52,625)	$ (30,834)	$ (19,702)
Denominator:			
Weighted average common shares outstanding, basic and diluted	34,261,548	23,198,400	4,978,539
Net loss per share attributable to common stockholders, basic and diluted	$ (1.54)	$ (1.33)	$ (3.96)

Included within weighted average common shares outstanding are common shares issuable upon the exercise of the pre-funded warrants as the warrants are exercisable at any time for nominal consideration, and as such, the shares are considered outstanding for the purpose of calculating basic and diluted net loss per share attributable to common stockholders.

The Company's potentially dilutive securities, which include stock options, preferred stock and warrants to purchase shares of series seed preferred stock, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

10. Net loss per share (Continued)

computation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	Year Ended March 31,		
	2020	2019	2018
Options to purchase common stock	4,964,381	3,721,784	2,520,247
Convertible preferred stock (as converted to common stock)	—	—	19,157,360
Warrants to purchase convertible preferred stock (as converted to common stock)	497,344	497,344	497,344
	5,461,725	4,219,128	22,174,951

11. Significant agreements

Agreement with Bristol-Myers Squibb Company

In February 2018, the Company entered into an agreement with Bristol-Myers Squibb Company ("BMS"). Pursuant to the agreement, BMS will provide to the Company, at no cost, a compound for use in the Company's ongoing clinical trial. Under the agreement, the Company will sponsor, fund and conduct the clinical trial in accordance with an agreed-upon protocol. BMS granted the Company a non-exclusive, non-transferrable, royalty-free license (with a right to sublicense) under its intellectual property to its compound in the clinical trial and agreed to supply its compound, at no cost to the Company, for use in the clinical trial. In January 2020, this agreement was expanded to cover an additional cohort of 125 patients with anti-PD-1 refractory melanoma.

Unless earlier terminated, the agreement will remain in effect until (i) the completion of the clinical trial, (ii) all related clinical trial data have been delivered to both parties and (iii) the completion of any statistical analyses and bioanalyses contemplated by the clinical trial protocol or any analysis otherwise agreed upon by the parties. The agreement may be terminated by either party (i) in the event of an uncured material breach by the other party, (ii) in the event the other party is insolvent or in bankruptcy proceedings or (iii) for safety reasons. Upon termination, the licenses granted to the Company to use BMS's compound in the clinical trial will terminate.

As of March 31, 2020, the Company had not incurred any costs and does not expect to incur future costs in connection with this agreement.

In April 2019, the Company entered into a separate agreement with BMS on terms similar to the terms set forth in the agreement described above, pursuant to which BMS will provide to the Company, at no cost, nivolumab for use in the Company's Phase 1 clinical trial of RP2 in combination with nivolumab.

Agreement with Regeneron Pharmaceuticals, Inc.

In May 2018, the Company entered into an agreement with Regeneron Pharmaceuticals, Inc. ("Regeneron"). The Company and Regeneron are each independently developing compounds for the treatment of certain tumor types. Pursuant to the agreement, the Company and Regeneron will undertake one or more clinical trials using a combination of the compounds being developed by each

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

11. Significant agreements (Continued)

entity. Under the agreement, each study will be conducted under terms set out in a separately agreed upon study plan that will identify the name of the sponsor and which party will manage the particular clinical trial, and include the protocol, the budget and a schedule of clinical obligations. In June 2018, under the terms of the agreement between the Company and Regeneron, the parties agreed to the first study plan. The Company and Regeneron have agreed to the protocol, budget, sample testing and clinical obligations schedule under the study plan. Development and supply costs associated with the study plan will be split equally between the Company and Regeneron.

Pursuant to the terms of the agreement, each party granted the other party a non-exclusive license under its respective intellectual property and agreed to contribute the necessary resources needed to fulfill its respective obligations, in each case, under the terms of the agreed-upon or to-be agreed upon study plans. Development costs of a particular clinical trial will be split equally between the Company and Regeneron.

The agreement may be terminated by either party if (i) there is no active study plan for which a final study report has not been completed, (ii) the parties have not entered into a study plan for an additional clinical trial within a period of time after the delivery of the most recent final study report or (iii) in the event of a material breach.

The Company will account for costs incurred as part of the study, including costs to supply compounds for use in the study, as research and development expenses within the consolidated statement of operations. The Company will recognize any amounts received from Regeneron in connection with this agreement as an offset to research and development expense within the consolidated statement of operations.

Under the terms of the agreement, on a quarterly basis the Company and Regeneron true-up costs of the study and make corresponding payments to the party that incurred the majority of the costs. During the year ended March 31, 2020, the Company did not receive or make any payments under the terms of the agreement to Regeneron. As of March 31, 2020 and 2019, the Company recorded $971 and $337 of receivables from Regeneron in connection with this agreement in prepaid expenses and other current assets in the consolidated balance sheet, respectively.

12. Commitments and contingencies

Leases

In December 2015, the Company entered into a lease agreement for office space in Woburn, Massachusetts, which expires on March 30, 2021. The Company has the option to extend the lease agreement for successive periods of five years. Monthly lease payments, inclusive of base rent and ancillary charges, total $7. Monthly base rent is subject to increase each year in proportion to the Consumer Price Index. The lease was terminated by the Company in March 2020, prior to the expiration of the lease term.

In April 2016, the Company entered into a lease agreement for office and laboratory space in Abingdon, England, which expires on April 3, 2026. The Company has the right to terminate the lease as of April 4, 2021 upon at least nine months' prior written notice. Monthly lease payments are inclusive of base rent, ancillary charges, non-rent shared tenant occupancy costs and the respective

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

12. Commitments and contingencies (Continued)

value added tax to be paid. Monthly lease payments include base rent of approximately $23 through December 3, 2016 and $31 thereafter. Monthly base rent is subject to increase after April 2021 in proportion to the Retail Price Index. The lease is classified as an operating lease.

In June 2018, the Company entered into an agreement to lease approximately 63,000 square feet of office, manufacturing and laboratory space in Framingham, Massachusetts. Pursuant to the lease agreement, the lease term commenced in December 2018, subject to the landlord completing certain agreed upon landlord improvements. The rent commencement date started in August 2019. The initial lease term is ten years from the rent commencement date and includes two optional five-year extensions. Annual lease payments during the first year were $2,373 with increases of 3.0% each year thereafter until the expiration of the lease.

Prior to the adoption of ASC 842 on April 1, 2019, the Company was deemed to be the accounting owner of the leased space during the construction period, which began in December 2018, because of certain indemnification provisions within the lease agreement. As a result, the Company had capitalized $11,514 as a build-to-suit lease asset within property and equipment as of March 31, 2019. Upon transition to ASC 842 on April 1, 2019, the Company determined that it did not control the build-to-suit lease asset and the arrangement has been accounted for under the guidance set forth within ASC 842, leases. Upon the adoption of ASC 842, the Company derecognized $11,514 of the build-to-suit lease asset and $6,561 of financing obligations and recorded long term prepaid rent of $5,006 on the consolidated balance sheet as landlord owned tenant improvements were determined to be prepaid rent under the guidance set forth within ASC 842. The Company continued to record construction costs incurred during the construction period subsequent to April 1, 2019 as prepaid rent.

Construction was completed associated with approximately 10,500 square feet of the leased space in Framingham, Massachusetts and the Company occupied the building as office space beginning August 1, 2019. The Company recorded a right-of-use asset and lease liability associated with the occupied space as of August 1, 2019. The Company recorded $2,368 in related construction costs to the right-of-use asset upon the lease commencement date which were reclassified from prepaid rent. The Company occupied the remainder of the facility, approximately 53,000 square feet used as laboratory space, on October 22, 2019. The Company recorded a right-of-use asset and lease liability associated with the remaining space as of October 22, 2019. The Company recorded $18,164 in related construction costs and $261 in rent payments made prior to the lease commencement date to the right-of-use asset upon the lease commencement date which were reclassified from prepaid rent. The lease is classified as a financing lease.

In June 2019, the Company entered into an agreement to lease approximately 18,700 square feet of office space in Woburn, Massachusetts. Pursuant to the lease agreement, the lease term commenced in August 2019. The rent commenced in September 2019. The initial lease term is ten years from the rent commencement date and includes an optional five-year extension. Annual lease payments during the first year are $488 with increases of approximately 1.6% each year. The Company recorded a right-of-use asset and a lease liability of $4,363 upon the commencement date of the lease and the lease is classified as an operating lease.

The Company determines if an arrangement is a lease at inception. Operating leases are included in our balance sheet as right-to-use—operating leases, operating lease liabilities, current and operating

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

12. Commitments and contingencies (Continued)

lease liabilities, non-current. Finance leases are included in the balance sheet as right-to-use asset—finance lease finance lease liabilities, current, and finance lease liabilities, non-current. Certain of the Company's lease agreements contain renewal options; however, the Company does not recognize right-of-use assets or lease liabilities for renewal periods unless it is determined that the Company is reasonably certain of renewing the lease at inception or when a triggering event occurs. As the Company's leases do not provide an implicit rate, the Company estimated the incremental borrowing rate in calculating the present value of the lease payments. Since the Company elected to account for each lease component and its associated non-lease components as a single combined lease component, all contract consideration was allocated to the combined lease component. Some of the Company's lease agreements contain rent escalation clauses (including index-based escalations). The Company recognizes the minimum rental expense on a straight-line basis based on the fixed components of a lease arrangement. The Company amortizes this expense over the term of the lease beginning with the date of initial possession, which is the date the Company can enter the leased space and begin to make improvements in preparation for its intended use. Variable lease components represent amounts that are not fixed in nature and are not tied to an index or rate, and are recognized as incurred.

	Year Ended March 31, 2020
Lease cost	
Finance lease costs:	
Amortization of right-to-use asset	$ 1,274
Interest on lease liabilities	1,185
Operating lease costs	885
Total lease cost	$ 3,344

Finance lease costs of $239 are recognized in general and administrative expenses for the year ended March 31, 2020 and $1,034 in research and development expenses for the year ended March 31, 2020. Operating leases costs are recognized in general and administrative expenses for the year ended March 31, 2020. The following table summarizes the maturity of the Company's lease liabilities on an

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

12. Commitments and contingencies (Continued)

undiscounted cash flow basis and a reconciliation to the operating and financing lease liabilities recognized on our balance sheet as of March 31, 2020:

	March 31,2020		
	Operating leases	Financing lease	Total
2021	$ 873	$ 2,411	$ 3,284
2022	586	2,483	3,069
2023	596	2,558	3,154
2024	605	2,634	3,239
2025	614	2,714	3,328
Thereafter	2,791	43,685	46,476
Total lease payments	6,065	56,485	62,550
Less : interest	1,455	29,107	30,562
Total lease liabilities	$ 4,610	$ 27,378	$ 31,988

The following table summarizes the future minimum lease payments due under the Company's operating leases as of March 31, 2019:

2020	$ 2,062
2021	2,901
2022	2,493
2023	2,568
2024	2,645
2025	2,725
Thereafter	12,770
	$ 28,164

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

12. Commitments and contingencies (Continued)

The following table provides lease disclosure as of and for the year ended March 31, 2020:

Leases	March 31, 2020
Right-to-use operating lease asset	$ 4,425
Right-to-use finance lease asset	46,925
Total lease assets	$ 51,350
Operating lease liabilities, current	$ 873
Finance lease liabilities, current	2,411
Operating lease liabilities, non-current	3,737
Finance lease liabilities, non-current	24,967
Total lease liabilities	$ 31,988
Other information	
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows from operating leases	$ 747
Operating cash flows from finance leases	$ 1,185
Financing cash flows from finance leases	$ 59
Right-to-use asset obtained in exchange for new operating lease liabilities	$ 5,152
Right-to-use asset obtained in exchange for new financing lease liabilities	$ 48,224
Variable lease costs	$ —
Short term lease costs	$ —
Weighted-average remaining lease term—operating leases	8.7 years
Weighted-average remaining lease term—financing leases	19.3 years
Weighted-average discount rate—operating leases	7%
Weighted-average discount rate—financing leases	8%

The variable lease costs and short-term lease costs were insignificant for the year ended March 31, 2020.

Manufacturing commitments

The Company has entered into an agreement with a contract manufacturing organization to provide clinical trial products. As of March 31, 2020, the Company had committed to minimum payments under these arrangements totaling $3,569 through March 31, 2021. As of March 31, 2019, the Company had committed to minimum payments under these arrangements totaling $4,694 through March 31, 2020.

Indemnification agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

12. Commitments and contingencies (Continued)

infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any claims under indemnification arrangements, and therefore it has not accrued any liabilities related to such obligations in its consolidated financial statements as of March 31, 2020 or 2019.

Legal proceedings

The Company is not a party to any litigation and does not have contingency reserves established for any litigation liabilities.

13. Benefit plans

The Company established a defined-contribution savings plan under Section 401(k) of the Code (the "401(k) Plan"). The 401(k) Plan covers substantially all employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. Matching contributions to the 401(k) Plan may be made at the discretion of the Company's board of directors. During the years ended March 31, 2020, 2019 and 2018, the Company made contributions totaling $232, $102 and $49, respectively, to the 401(k) Plan.

We provide a pension contribution plan for our employees in the United Kingdom, pursuant to which we match our employees' contributions each year in amounts up to 8% of their annual base salary.

14. Income taxes

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") was enacted in the United States. The CARES Act provides numerous tax provisions and other stimulus measures, including temporary changes regarding the prior and future utilization of net operating losses and technical corrections from prior tax legislation for tax depreciation of certain qualified improvement property. We evaluated the provisions of the CARES Act and do not anticipate the associated impacts, if any, will have a material effect on our financial position.

During the years ended March 31, 2020, 2019 and 2018, the Company recorded no income tax benefits for the net operating losses incurred generated during the years then ended, due to its uncertainty of realizing a benefit from those items. The Company's net loss before income taxes were generated in the United States and the United Kingdom.

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

14. Income taxes (Continued)

Net loss before income taxes for the years ended March 31, 2020, 2019 and 2018 were as follows:

	Year Ended March 31,		
	2020	2019	2018
United States	$ (12,963)	$ (9,483)	$ (8,992)
Foreign (United Kingdom)	(39,662)	(21,351)	(10,710)
	$ (52,625)	$ (30,834)	$ (19,702)

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate for the years ended March 31, 2020, 2019 and 2018 is as follows:

	March 31,		
	2020	2019	2018
U.S. Federal statutory income tax rate	(21.00)%	(21.00)%	(21.00)%
State taxes, net of federal benefit	(1.6)	(1.5)	(2.6)
Research and development expenses	2.2	3.1	3.8
Remeasurement of deferred taxes as a result of tax reform	—	—	2.6
Foreign tax rate differential	2.8	2.4	2.2
Change in valuation allowance	16.0	15.5	14.0
Return to provision	1.9	0.4	—
Other	(0.3)	1.1	1.0
Effective income tax rate	0.00%	0.00%	0.00%

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

14. Income taxes (Continued)

Components of the Company's deferred tax assets as of March 31, 2020 and 2019 were as follows:

	March 31, 2020	March 31, 2019
Deferred tax assets:		
Foreign net operating loss carryforwards	$ 9,092	$ 4,079
Federal net operating loss carryforwards	2,450	2,223
State net operating loss carryforwards	1,054	684
Property, plant and equipment	5,499	—
Capitalized start-up costs	1,748	1,886
Stock compensation	2,526	573
Accrued expenses	341	1,793
Lease liability	8,705	—
Total deferred tax assets	31,415	11,238
Deferred tax liabilities:		
Right-to-use asset	(13,998)	—
Property, plant and equipment	—	(1,842)
Other	(88)	—
Total deferred tax liabilities	(14,086)	(1,842)
Valuation allowance	(17,329)	(9,396)
Net deferred tax assets	$ —	$ —

As of March 31, 2020, the Company had federal and foreign net operating loss carryforwards of approximately $11,667 and $53,483, respectively, which can be carried forward indefinitely. As of March 31, 2020, the Company had state net operating loss carryforwards of $ 16,670, which will expire between 2039 and 2040.

Utilization of the U.S. federal and state net operating loss carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of net operating loss carryforwards that can be utilized annually to offset future taxable income and tax liabilities, respectively. The Company has not completed a study to assess whether a change of ownership has occurred, or whether there have been multiple ownership changes since its formation, due to the significant cost and complexity associated with such a study. Any limitation may result in expiration of a portion of the net operating loss carryforwards before utilization. Further, until a study is completed by the Company and any limitation is known, no amounts are being presented as an uncertain tax position.

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

14. Income taxes (Continued)

Changes in the valuation allowance for deferred tax assets during the years ended March 31, 2020 and 2019 related primarily to the increase in net operating loss carryforwards were as follows:

	March 31,	
	2020	2019
Valuation allowance as of beginning of year	$ 9,396	$ 4,724
Increases recorded to income tax provision	8,047	4,672
Decreases recorded to income tax provision for equity	(114)	—
Valuation allowance as of end of year	$ 17,329	$ 9,396

As of March 31, 2020 and 2019, the Company had not recorded any amounts for unrecognized tax benefits. The Company's policy is to record interest and penalties related to income taxes as part of its income tax provision. As of March 31, 2020 and 2019, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts had been recognized in the Company's consolidated statements of operations and comprehensive loss.

The Company files income tax returns in the United States, Massachusetts and the United Kingdom as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by U.S. federal, state and foreign jurisdictions, where applicable. There are currently no pending tax examinations. The Company is open to future tax examination in the U.S. under statute from 2017 to the present and in the United Kingdom from 2016 to the present.

15. Geographic information

The Company operates in two geographic regions: the United States (Massachusetts) and the United Kingdom (Oxfordshire). Information about the Company's long-lived assets held in different geographic regions is presented in the tables below:

	March 31,	
	2020	2019
United States	$ 6,357	11,648
United Kingdom	503	511
	$ 6,860	$ 12,159

REPLIMUNE GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share amounts)

16. Quarterly financial data (unaudited)

The following information has been derived from unaudited consolidated financial statements that, in the opinion of management, include all recurring adjustments necessary for a fair statement of such information.

	Three Months Ended			
	March 31, 2020	December 31, 2019	September 30, 2019	June 30, 2019
Operating expenses	16,385	16,664	12,242	10,907
Net loss attributable to common stockholders	(15,789)	(16,189)	(11,139)	(9,508)
Net loss per share attributable to common stockholders, basic and diluted	(0.41)	(0.46)	(0.35)	(0.30)

	Three Months Ended			
	March 31, 2019	December 31, 2018	September 30, 2018	June 30, 2018
Operating expenses	7,826	10,137	7,104	5,879
Net loss attributable to common stockholders	(6,656)	(7,673)	(6,461)	(10,044)
Net loss per share attributable to common stockholders, basic and diluted	(0.29)	(0.24)	(0.26)	(2.02)

17. Subsequent events

For its consolidated financial statements as of March 31, 2020 and for the year then ended, the Company evaluated subsequent events through the date on which those financial statements were issued.

Hercules Loan Agreement

On June 1, 2020, the Company amended the Hercules Loan Agreement to increase the secured term loan facility from $30,000 to $40,000 by adding a fourth advance of up to $10,000 which may be borrowed between July 1, 2021 and December 15, 2021. The amended agreement contains certain borrowing milestones as defined in the agreement. Additionally, the Amortization Date was changed from March 1, 2022 to September 1, 2022 to extend the interest only payment period by six months

Exhibit 3.1

THIRD AMENDED AND RESTATED
CERTIFICATE OF INCORPORATION OF
REPLIMUNE GROUP, INC.

Replimune Group, Inc., a corporation organized and existing under the laws of the State of Delaware (the "Corporation"), **DOES HEREBY CERTIFY:**

FIRST: The name of the Corporation is "Replimune Group, Inc." The date of filing the original Certificate of Incorporation of the Corporation with the Secretary of State of the State of Delaware was July 5, 2017.

SECOND: This Third Amended and Restated Certificate of Incorporation (this "Restated Certificate") has been duly approved by the Board of Directors of the Corporation.

THIRD: This Restated Certificate has been duly adopted by the stockholders of the Corporation in accordance with the provisions of Sections 228, 242 and 245 of the General Corporation Law of the State of Delaware (the "DGCL"), and notice thereof has been given in accordance with the provisions of Section 228 of the DGCL.

FOURTH: The Certificate of Incorporation of this Corporation is hereby amended, integrated and restated to read as follows:

ARTICLE ONE

The name of the Corporation is Replimune Group, Inc.

ARTICLE TWO

The address of the registered office of the Corporation in the State of Delaware is 1209 Orange Street, in the City of Wilmington, County of New Castle 19801. The name of the registered agent at such address is The Corporation Trust Company.

ARTICLE THREE

The nature of the business or purpose of the Corporation is to engage in any lawful act or activity for which corporations may be organized under the DGCL.

ARTICLE FOUR

Section 1. Authorized Shares. The total number of shares of all classes of capital stock which the Corporation shall have authority to issue is One Hundred Sixty Million (160,000,000) shares, consisting of:

(a) One Hundred Fifty Million (150,000,000) shares of common stock, par value $0.001 per share ("Common Stock"); and

(b) Ten Million (10,000,000) shares of undesignated preferred stock, par value $0.001 per share (the "Preferred Stock").

Such stock may be issued from time to time by the Corporation for such consideration as may be fixed by the board of directors of the Corporation (the "Board of Directors"). The following is a statement of the powers, designations, preferences, privileges, and relative rights in respect of each class of capital stock of the Corporation.

Section 2. Common Stock.

(a) General. The voting, dividend and liquidation rights of the holders of Common Stock are subject to and qualified by the rights of the holders of Preferred Stock.

(b) Voting. Except as otherwise provided by the DGCL or this Restated Certificate and subject to the rights of holders of any series of Preferred Stock, all of the voting power of the stockholders of the Corporation shall be vested in the holders of the Common Stock, and each holder of Common Stock shall have one vote for each share held by such holder on all matters voted upon by the stockholders of the Corporation; provided, however, that, except as otherwise required by law, holders of Common Stock, as such, shall not be entitled to vote on any amendment to this Restated Certificate (or on any amendment to a certificate of designations of any series of Preferred Stock) that alters or changes the powers, preferences, rights or other terms of one or more outstanding series of Preferred Stock if the holders of such affected series of Preferred Stock are entitled to vote, either separately or together with the holders of one or more other such series, on such amendment pursuant to this Restated Certificate (or pursuant to a certificate of designations of any series of Preferred Stock) or pursuant to the DGCL. There shall be no cumulative voting.

(c) Dividends. Except as otherwise provided by the DGCL or this Restated Certificate, dividends may be declared and paid on the Common Stock from funds lawfully available therefor if, as and when determined by the Board of Directors and subject to any preferential dividend rights of any then outstanding shares of Preferred Stock.

(d) No Preemptive Rights. The holders of the Common Stock shall have no preemptive rights to subscribe for any shares of any class of stock of the Corporation whether now or hereafter authorized.

(e) No Conversion Rights. The Common Stock shall not be convertible into, or exchangeable for, shares of any other class or classes or of any other series of the same class of the Corporation's capital stock.

(f) Liquidation. Upon the dissolution or liquidation or winding up of the affairs of the Corporation, whether voluntary or involuntary, holders of Common Stock will be entitled to receive all assets of the Corporation available for distribution to its stockholders equally on a per share basis, subject to any preferential rights of any then outstanding shares of Preferred Stock and after payment or provision for payment of the Corporation's debts.

Section 3. Preferred Stock. To the fullest extent authorized by the DGCL, shares of Preferred Stock may be issued from time to time in one or more series, each of such series to have such powers, designations, preferences, and relative, participating, optional, or other special rights, if any, and such qualifications and restrictions, if any, as are stated or expressed in the resolution or resolutions of the Board of Directors providing for such series of Preferred Stock. Different series of Preferred Stock shall not be construed to constitute different classes of shares for the purposes of voting by classes unless expressly so provided in such resolution or resolutions.

Authority is hereby granted to the Board of Directors, acting by resolution or resolutions adopted at any time and from time to time, to create, provide for, designate and issue, out of the authorized but unissued shares of Preferred Stock, one or more series of Preferred Stock, and, in connection with the creation of any such series of Preferred Stock, to determine and fix the powers, designations, preferences, and relative, participating, optional, or other special rights, if any, and the qualifications and restrictions, if any, including without limitation dividend rights, conversion rights, voting rights (if any), redemption privileges, and liquidation preferences, of such series of Preferred Stock (which need not be uniform among series), all to the fullest extent now or hereafter permitted by the DGCL. Without limiting the generality of the foregoing, the resolution or resolutions providing for the creation or issuance of any series of Preferred Stock may provide that such series shall be superior to, rank equally with, or be junior to any other series of Preferred Stock, all to the fullest extent permitted by law. No resolution, vote, or consent of the holders of the capital stock of the Corporation shall be required in connection with the creation or issuance of any shares of any series of Preferred Stock authorized by and complying with the conditions of this Restated Certificate, the right to any such resolution, vote, or consent being expressly waived by all present and future holders of the capital stock of the Corporation.

Any resolution or resolutions adopted by the Board of Directors pursuant to the authority vested in them by this Section 3 of Article Four shall be set forth in a certificate of designation along with the number of shares of such series of Preferred Stock as to which the resolution or resolutions shall apply and such certificate shall be executed,

acknowledged, filed, recorded, and shall become effective, in accordance with Section 103 of the DGCL. Unless otherwise provided in any such resolution or resolutions, the number of shares of any such series of Preferred Stock to which such resolution or resolutions apply may be increased (but not above the total number of authorized shares of Preferred Stock) or decreased (but not below the number of shares of such series of Preferred Stock then outstanding) by a certificate likewise executed, acknowledged, filed and recorded, setting forth a statement that a specified increase or decrease therein has been authorized and directed by a resolution or resolutions likewise adopted by the Board of Directors. In case the number of such shares shall be decreased, the number of shares so specified in the certificate shall resume the status which they had prior to the adoption of the first resolution or resolutions. When no shares of any such series of Preferred Stock are outstanding, either because none were issued or because none remain outstanding, a certificate setting forth a resolution or resolutions adopted by the Board of Directors that none of the authorized shares of such series of Preferred Stock are outstanding, and that none will be issued subject to the certificate of designations previously filed with respect to such series of Preferred Stock, may be executed, acknowledged, filed and recorded in the same manner as previously described and it shall have the effect of eliminating from this Restated Certificate all matters set forth in the certificate of designations with respect to such series of Preferred Stock. If no shares of any such series of Preferred Stock established by a resolution or resolutions adopted by the Board of Directors have been issued, the voting powers, designations, preferences and relative, participating, optional or other rights, if any, with the qualifications, limitations or restrictions thereof, may be amended by a resolution or resolutions adopted by the Board of Directors. In the event of any such amendment, a certificate which (i) states that no shares of such series of Preferred Stock have been issued, (ii) sets forth the copy of the amending resolution or resolutions and (iii) if the designation of such series of Preferred Stock is being changed, indicates the original designation and the new designation, shall be executed, acknowledged, filed, recorded, and shall become effective, in accordance with Section 103 of the DGCL.

ARTICLE FIVE

The Corporation is to have perpetual existence.

ARTICLE SIX

Section 1. Classification of Directors. Effective as of the closing (the "IPO Closing") of the Corporation's first public offering of shares of Common Stock registered pursuant to the Securities Act of 1933, as amended, the Board of Directors shall be divided into three classes of directors, Class I, Class II, and Class III, such classes to be as nearly equal in number of directors as possible, having staggered three-year terms of office (except to the extent otherwise provided in the next sentence with respect to the initial terms of such classes of directors). The initial term of office of the directors of Class I shall expire as of the first annual meeting of the Corporation's stockholders following the IPO Closing; the initial term of office of the directors of Class II shall expire as of the second annual meeting of the Corporation's stockholders following the IPO Closing; and the initial term of office of the directors of Class III shall expire as of the third annual meeting of the Corporation's stockholders following the IPO Closing. At each annual meeting of stockholders of the Corporation after the IPO Closing, nominees will stand for election to succeed those directors whose terms are to expire as of such annual meeting of stockholders, and such nominees elected at such annual meeting of stockholders shall be elected for a term expiring at the third annual meeting of stockholders following their election. Directors shall hold office until the annual meeting of stockholders in which their term is scheduled to expire as set forth above in this Section 1 of Article Six and until their respective successors are duly elected or qualified or until their earlier death, incapacity, resignation or removal. Those directors already in office immediately prior to the IPO Closing shall be allocated among the three classes of directors contemplated under this Section 1 of Article Six pursuant to a resolution or resolutions adopted by the Board of Directors prior to the IPO Closing.

Section 2. Removal. Subject to the special rights of the holders of any series of Preferred Stock to elect directors, the directors of the Corporation may be removed only for cause by the affirmative vote of the holders of at least seventy-five percent (75%) of the outstanding shares of capital stock of the Corporation entitled to vote in the election of directors or class of directors, voting together as a single class, at a meeting of the stockholders called for that purpose.

Section 3. Vacancies. Except as the DGCL may otherwise require, any new directorships or vacancies in the Board of Directors, including new directorships resulting from any increase in the number of directors to serve in

the Board of Directors and/or any unfilled vacancies by reason of death, resignation, disqualification, removal for cause, failure to elect or otherwise with respect to any director, may be filled only by the vote of a majority of the remaining directors then in office, although less than a quorum, or by the sole remaining director.

Section 4. Number of Directors. Subject to the special rights of the holders of any series of Preferred Stock to elect directors, the number of directors which shall constitute the Board of Directors shall be fixed exclusively by the Board of Directors from time to time in accordance with the by-laws of the Corporation. No decrease in the number of directors constituting the whole board shall shorten the term of any incumbent director.

ARTICLE SEVEN

The Board of Directors shall have the power and authority: (i) to adopt, amend or repeal the Corporation's by-laws, subject to the power of the stockholders of the Corporation entitled to vote with respect thereto to make, alter, amend or repeal the by-laws; provided, that with respect to the powers of stockholders entitled to vote with respect thereto to make, alter, amend or repeal the by-laws, in addition to any other vote otherwise required by law, the affirmative vote of the holders of at least seventy-five percent (75%) of the outstanding shares of capital stock of the Corporation entitled to vote in the election of directors or class of directors, voting together as a single class, shall be required to make, alter, amend or repeal the by-laws of the Corporation; and (ii) to the full extent permitted or not prohibited by law, and without the consent of or other action by the stockholders, to authorize or create mortgages, pledges or other liens or encumbrances upon any or all of the assets, real, personal or mixed, and franchises of the Corporation, including after-acquired property, and to exercise all of the powers of the Corporation in connection therewith.

ARTICLE EIGHT

Except as otherwise provided for by any resolutions of the Board of Directors providing for the issuance of any series of Preferred Stock, effective as of the IPO Closing, any action required or permitted to be taken by the stockholders of the Corporation may be taken only at a duly called annual or special meeting of the stockholders in which such action is properly brought before such meeting, and not by written consent in lieu of such a meeting. Subject to any special rights of the holders of any series of Preferred Stock, and to the requirements of applicable law, special meetings of stockholders of the Corporation may be called only by or at the direction of the Board of Directors pursuant to a resolution adopted by a majority of the total number of directors. Any business transacted at any special meeting of stockholders shall be limited to matters relating to the purpose or purposes stated in the notice of meeting.

ARTICLE NINE

The Corporation reserves the right to amend, alter, change or repeal any provision contained in this Restated Certificate, in the manner now or hereafter prescribed by the DGCL, and all rights conferred upon stockholders herein are granted subject to this reservation. Notwithstanding anything to the contrary contained in this Restated Certificate, and notwithstanding that a lesser percentage may be permitted from time to time by applicable law, the affirmative vote of the holders of at least seventy-five percent (75%) of the outstanding shares of capital stock of the Corporation entitled to vote in the election of directors or class of directors, voting together as a single class (in addition to any separate class vote that may in the future be required pursuant to the terms of any outstanding Preferred Stock), shall be required to amend or repeal the provisions of Articles Four (only to the extent it relates to the authority of the Board of Directors to issue shares of Preferred Stock in one or more series, the terms of which may be determined by the Board of Directors), Six, Seven, Eight, Nine, Ten, or Eleven of this Restated Certificate or to reduce the numbers of authorized shares of Common Stock or Preferred Stock.

ARTICLE TEN

Section 1. Limitation of Liability. To the fullest extent permitted by the DGCL as it now exists or may hereafter be amended (but, in the case of any such amendment, only to the extent that such amendment permits the Corporation to provide broader indemnification rights than permitted prior thereto), no director of the Corporation shall be personally liable to the Corporation or to any of its stockholders for monetary damages for breach of fiduciary duty as a director, notwithstanding any provision of law imposing such liability; provided, however, that to

the extent required from time to time by applicable law, this Article Ten shall not eliminate or limit the liability of a director, to the extent such liability is provided by applicable law, (i) for any breach of the director's duty of loyalty to the corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) under Section 174 of the DGCL, or (iv) for any transactions from which the director derived an improper personal benefit.

Section 2. Indemnification. The Corporation shall, to the fullest extent permitted by Section 145 of the DGCL and as further provided in the Corporation's by-laws, each as amended from time to time, indemnify each person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that such person is or was, or has agreed to become, a director or officer of the Corporation, or is or was serving, or has agreed to serve, at the request of the Corporation, as a director, officer or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (including any employee benefit plan), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by him or her or on his or her behalf in connection with such action, suit or proceeding and any appeal therefrom.

Indemnification may include payment by the Corporation of expenses in defending an action or proceeding in advance of the final disposition of such action or proceeding upon receipt of an undertaking by the person indemnified to repay such payment if it is ultimately determined that such person is not entitled to indemnification under this Article Ten, which undertaking may be accepted without reference to the financial ability of such person to make such repayment.

The Corporation shall not indemnify any such person seeking indemnification in connection with a proceeding (or part thereof) initiated by such person unless the initiation thereof was approved by the Board of Directors or except and to the extent otherwise permitted in the Corporation's by-laws or in an agreement between the Corporation and such person.

The indemnification rights provided in this Article Ten (i) shall not be deemed exclusive of any other rights to which those indemnified may be entitled under the Corporation's by-laws, any law, agreement or vote of stockholders or disinterested directors or otherwise, and (ii) shall inure to the benefit of the heirs, executors and administrators of such persons. The Corporation may, to the extent authorized from time to time by its Board of Directors, grant indemnification rights to other employees or agents of the Corporation or other persons serving the Corporation and such rights may be equivalent to, or greater or less than, those set forth in this Article Ten.

Section 3. Merger or Consolidation. For purposes of this Article Ten, references to the "Corporation" shall include, in addition to the resulting corporation, any constituent corporation (including any constituent of a constituent) absorbed in a consolidation or merger which, if its separate existence had continued, would have had power and authority to indemnify its directors, officers and employees or agents, so that any person who is or was a director, officer, employee or agent of such constituent corporation, or is or was serving at the request of such constituent corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, shall stand in the same position under this Article Ten with respect to the resulting or surviving corporation as he or she would have with respect to such constituent corporation if its separate existence had continued.

Section 4. Amendment or Repeal. No amendment to or repeal of this Article Ten shall apply to or have any effect on the liability or alleged liability of any director for or with respect to any acts or omissions of such director occurring prior to the effective date of such amendment or repeal.

ARTICLE ELEVEN

Unless the Corporation, as authorized by the Board of Directors, consents in writing to the selection of one or more alternative forums, the Court of Chancery of the State of Delaware (or if the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware) shall, to the fullest extent permitted by law, be the sole and exclusive forum for a stockholder (including a beneficial owner) to bring (i) any derivative action or proceeding brought on behalf of the Corporation, (ii) any action asserting a claim of breach of a fiduciary duty owed

by any director, officer or other employee of the Corporation to the Corporation or the Corporation's stockholders, (iii) any action asserting a claim against the Corporation arising pursuant to any provision of the DGCL or this Restated Certificate or the Corporation's by-laws or (iv) any action asserting a claim against the Corporation, its directors, officers or employees governed by the internal affairs doctrine; except for, as to each of (i) through (iv) above, any claim (A) as to which such court determines that there is an indispensable party not subject to the jurisdiction of such court (and the indispensable party does not consent to the personal jurisdiction of such court within ten (10) days following such determination), (B) which is vested in the exclusive jurisdiction of a court or forum other than such court, or (C) for which such court does not have subject matter jurisdiction. Notwithstanding the foregoing, nothing in this Article Eleven shall preclude or contract the scope of exclusive federal or concurrent jurisdiction for actions brought under the U.S. Securities Act of 1933, as amended, or the U.S. Securities Exchange Act of 1934, as amended, or the respective rules and regulations promulgated thereunder, or otherwise limit the rights of any stockholder (including a beneficial owner) to bring any claim under such laws, rules or regulations in any United States federal district court of competent jurisdiction. Any person or entity purchasing or otherwise acquiring any interest in shares of capital stock of the Corporation (including, without limitation, shares of Common Stock) shall, and shall be deemed to, have notice of and to have consented to the provisions of this Article Eleven.

ARTICLE TWELVE

If any provision or provisions of this Restated Certificate shall be held to be invalid, illegal or unenforceable as applied to any circumstance for any reason whatsoever: (i) the validity, legality and enforceability of such provisions in any other circumstance and of the remaining provisions of this Restated Certificate (including, without limitation, each portion of any paragraph of this Restated Certificate containing any such provision held to be invalid, illegal or unenforceable that is not itself held to be invalid, illegal or unenforceable) shall not in any way be affected or impaired thereby and (ii) to the fullest extent possible, the provisions of this Restated Certificate (including, without limitation, each such portion of any paragraph of this Restated Certificate containing any such provision held to be invalid, illegal or unenforceable) shall be construed so as to permit the Corporation to protect its directors, officers, employees and agents from personal liability in respect of their good faith service to or for the benefit of the Corporation to the fullest extent permitted by law.

[The remainder of this page is left intentionally blank.]

IN WITNESS WHEREOF, this Third Amended and Restated Certificate of Incorporation has been executed by a duly authorized officer of this Corporation on this 24th day of July, 2018.

REPLIMUNE GROUP, INC.

By: /s/ Robert Coffin
Name: Robert Coffin
Title: President

[Signature Page to Third Amended and Restated Certificate of Incorporation of Replimune Group, Inc.]

Exhibit 4.3

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

The following description sets forth certain material terms and provisions of Replimune Group, Inc.'s ("we," "us," and "our") securities that are registered under Section 12 of the Securities Exchange Act of 1934, as amended.

DESCRIPTION OF CAPITAL STOCK

The following description is a summary and does not purport to be complete. It is subject to, and qualified in its entirety by reference to, our Third Amended and Restated Certificate of Incorporation, as amended (our "Certificate of Incorporation"), and our Amended and Restated By-laws (our "Bylaws"), each of which are incorporated by reference or filed as an exhibit to our Annual Report on Form 10-K of which this Exhibit 4.3 is a part. The terms of these securities also may be affected by the Delaware General Corporation Law (the "DGCL").

Authorized Capital Stock

The Company's authorized capital stock consists of 150,000,000 shares of common stock, par value $0.001 per share, and 10,000,000 shares of undesignated preferred stock, par value $0.001 per share.

Common Stock

Subject to any preferential rights that may be applicable to any outstanding shares of preferred stock from time to time, holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of the stockholders. The holders of our common stock do not have any cumulative voting rights. Holders of our common stock are entitled to receive ratably any dividends declared by our board of directors out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock. Our common stock has no preemptive rights, conversion rights or other subscription rights or redemption or sinking fund provisions.

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any liquidation preference of any outstanding preferred stock.

Preferred Stock

Pursuant to our Certificate of Incorporation, our board of directors has the authority, without further action by our stockholders, to designate up to 10,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of common stock.

The DGCL provides that the holders of preferred stock will have the right to vote separately as a class on any proposal involving fundamental changes in the rights of holders of that preferred stock. This right is in addition to any voting rights that may be provided for in the applicable certificate of designation.

Pre-Funded Warrants

In November 2019, we issued and sold 8 pre-funded warrants to purchase an aggregate of 2,200,000 shares of our common stock at an offering price of $13.6099 per pre-funded warrant in an underwritten public offering pursuant to a shelf registration on Form S-3.

Each pre-funded warrant entitles the holder to purchase one share of our common stock at an exercise price of $0.0001 per share. The pre-funded warrants do not expire and may be exercised at any time after their original issuance. Under the pre-funded warrants, we may not effect the exercise of any pre-funded warrant, and a holder will not be entitled to exercise any portion of any pre-funded warrant, which, upon giving effect to such exercise, would cause (i) the aggregate number of shares of our common stock beneficially owned by the holder (together with its affiliates) to exceed 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, or (ii) the combined voting power of our securities beneficially owned by the holder of the pre-funded warrant (together with its affiliates) to exceed 9.99% of the combined voting power of all of our securities then outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the pre-funded warrants. However, any holder may increase or decrease such percentage to any other percentage upon at least 61 days' prior notice from the holder to us. The exercise price of the pre-funded warrants and the number of shares of our common stock issuable upon exercise of the pre-funded warrants is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders. The exercise price will not be adjusted below the par value of our common stock.

Anti-Takeover Effects of Provisions of Delaware Law and Our Certificate of Incorporation and Bylaws

The provisions of Delaware law and of our Certificate of Incorporation and Bylaws may have the effect of discouraging, delaying or preventing a change in control or an unsolicited acquisition proposal that a stockholder might consider favorable, including a proposal that might result in the payment of a premium over the market price for the shares held by stockholders. These provisions are summarized in the following paragraphs.

Classified Board of Directors. Our Certificate of Incorporation and Bylaws provide that our board of directors is divided into three classes of directors, with the directors in each class serving staggered three-year terms and with the number of directors in each class to be as nearly equal as possible. The classification of our board of directors has the effect of requiring at least two annual stockholder meetings, instead of one, to replace a majority of the members of our board of directors.

Authorized but Unissued or Undesignated Capital Stock. Our authorized capital stock consists of 150,000,000 shares of common stock and 10,000,000 shares of preferred stock. The authorized but unissued (and in the case of preferred stock, undesignated) stock may be issued by our board of directors in one or more transactions. In this regard, our Certificate of Incorporation grants our board of directors broad power to establish the rights and preferences of authorized and unissued preferred stock. The issuance of shares of preferred stock pursuant to our board of directors' authority described above could decrease the amount of earnings and assets available for distribution to holders of common stock and adversely affect the rights and powers, including voting rights, of such holders and may have the effect of delaying, deferring or preventing a change in control. Our board of directors does not currently intend to seek stockholder approval prior to any issuance of preferred stock, unless otherwise required by law.

Special Meetings of Stockholders. Our Certificate of Incorporation provides that special meetings of the stockholders may be called only by or at the direction of our board of directors. Our Bylaws prohibit the conduct of any business at a special meeting other than as specified in the notice for such meeting.

Requirements for Advance Notification of Stockholder Nominations and Proposals. Our Bylaws establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of our board of directors or a committee of our board of directors. In order for any matter to be "properly brought" before a meeting, a stockholder will have to comply with advance notice requirements and provide us with certain information. Additionally, vacancies and newly created directorships may be filled only by a vote of a majority of the directors then in office, even though less than a quorum, and not by the stockholders. Our Bylaws allow the presiding officer at a meeting of the stockholders to adopt rules and regulations for the conduct of meetings which may have the effect of precluding the conduct of certain business at a meeting if the rules and regulations are not followed. These provisions may also defer, delay or discourage a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of our company.

Stockholder Action by Written Consent. Our Certificate of Incorporation prohibits the taking of any action of our stockholders by written consent without a meeting.

Amendments to Our Certificate of Incorporation and Bylaws. The DGCL provides that, unless a corporation's certificate of incorporation provides otherwise, the affirmative vote of holders of shares constituting a majority of the votes of all shares entitled to vote may approve amendments to the certificate of incorporation. Our Certificate of Incorporation and Bylaws provide that the affirmative vote of holders of at least 75% of the outstanding shares of capital stock, voting together as a single class, and entitled to vote in the election of directors, will be required to amend, alter, change or repeal our Certificate of Incorporation and Bylaws. This requirement of a supermajority vote to approve amendments to our Certificate of Incorporation and Bylaws could enable a minority of our stockholders to exercise veto power over such amendments.

No Cumulative Voting. The DGCL provides that stockholders are not entitled to cumulate votes in the election of directors unless the corporation's certificate of incorporation provides otherwise. Our Certificate of Incorporation does not expressly provide for cumulative voting.

Delaware Anti-Takeover Statute. We are governed by the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a public Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. A "business combination" includes mergers, asset sales or other transactions resulting in a financial benefit to the stockholder. An "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years of the date on which it is sought to be determined whether such person is an interested stockholder, did own, 15% or more of the corporation's outstanding voting stock. These provisions may have the effect of delaying, deferring, or preventing a change in our control.

Registration Rights

Certain holders of our common stock, or their transferees, are entitled to registration rights with respect to registration of the resale of such shares under the Securities Act of 1933, as amended, pursuant to the amended and restated investors' rights agreement, by and among us and certain of our investors.

Stock Exchange Listing

Our common stock is listed on the Nasdaq Global Select Market under the symbol "REPL."

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A.

Exhibit 10.13

Replimune Inc
18 Commerce Way
Woburn, MA 01801

PERSONAL & CONFIDENTIAL
BY HAND

March 30, 2020

Stephen Gorgol
5 Blackthorne Circle
Hopkinton, MA 01748

RE: Separation Agreement and Release

Dear Steve:

This letter of agreement and general release ("Agreement") confirms our mutual agreement regarding the terms and conditions of your separation from employment with Replimune, Inc. (the "Company"). You and the Company agree as follows:

1. Last Day of Employment. Your last day of employment with the Company will be March 31, 2020 ("Last Day of Employment"). You will receive your salary and other amounts earned, accrued and owing but not yet paid through your Last Day of Employment, including any benefits accrued and due under any applicable benefit plans and programs of the Company ("Accrued Obligations"), pursuant to your Employment Agreement with the Company dated May 8, 2019 (the "Employment Agreement"), regardless of whether you execute or revoke this Agreement. You will also receive payment for approved expenses provided you submit for such expenses by May 1st 2020. Your employment and your participation in and eligibility for the Company's employee benefit plans and programs will terminate on your Last Day of Employment.

2. Consideration in Exchange for Release. In consideration of your execution of this Agreement (provided you do not revoke it), and provided that you (a) that you do not revoke and that you continue to comply with this Agreement, and (b) otherwise comply with your obligations under this Agreement and your continuing obligations under Sections 15-17 of your Employment Agreement, attached hereto as Exhibit A, the Company will:

   (a) Enter into the consulting agreement attached here as Exhibit B with you (the "Consulting Agreement"), to be effective on the first business day following the Effective Date, and the Company will provide the compensation described therein upon performance of the services described therein; and

   (b) During the period beginning on the Last Day of Employment and ending on the earlier of (i) the date on which you first become covered by any other "group health plan" as described in section 4980B(g)(2) of the Internal Revenue Code of 1986, as amended (the "Code") or (ii) December 31, 2020 (the "Coverage Period"), if you elect to receive continued health coverage under the Company's health plan under

the Consolidated Omnibus Budget Reconciliation Act ("COBRA") at a level of coverage at or below your level of coverage in effect on the Last Day of Employment, the Company will pay the monthly COBRA premiums necessary to continue your coverage through the Coverage Period, as and when due to the insurance carrier or COBRA administrator (the "COBRA Payments"). You agree to promptly notify the Company of your coverage under an alternative health plan upon becoming covered by such alternative plan. The COBRA health care continuation coverage period under section 4980B of the Code shall run concurrently with the Coverage Period.

3. Release.

(a) In consideration of the compensation and benefits set forth in Section 2 hereof, to the fullest extent permitted by law you waive, release, and forever discharge the Company and each of its past and current parents, subsidiaries, affiliates, and each of its and their respective past and current directors, officers, members, trustees, employees, representatives, agents, attorneys, employee benefit plans and such plans' administrators, fiduciaries, trustees, recordkeepers and service providers, and each of its and their respective successors and assigns, each and all of them in their personal and representative capacities (collectively the "Company Releasees") from any and all claims legally capable of being waived, agreements, causes of action, attorneys' fees, costs, damages, or any right to any monetary recovery or any other personal relief, whether known or unknown, in law or in equity, by contract, tort, law of trust or pursuant to federal, state or local statute, regulation, ordinance or common law, which you now have, ever have had, or may hereafter have, whether known or unknown to you, arising at any time up to the date of execution of this Agreement, arising out of or relating in any way to your employment with the Company or the termination thereof.

Without limiting the generality of the foregoing, this waiver, release, and discharge includes any claim or right, to the extent legally capable of being waived, based upon or arising under any federal, state or local fair employment practices or equal opportunity laws, including, but not limited to, the Age Discrimination in Employment Act ("ADEA") (29 U.S.C. Section 621, et seq.), 42 U.S.C. Section 1981, Title VII of the Civil Rights Act of 1964, the Equal Pay Act, the Employee Retirement Income Security Act ("ERISA") (including, but not limited to, claims for breach of fiduciary duty under ERISA), the Americans With Disabilities Act, the Family and Medical Leave Act of 1993, the Massachusetts Fair Employment Practices Act, the Massachusetts Civil Rights Act, the Massachusetts Equal Rights Act, the Massachusetts Parental Leave Act, the Massachusetts Labor and Industries Act, the Massachusetts right of privacy law, the Massachusetts Wage Act (as further explained below), the Massachusetts Earned Sick Time law, the Massachusetts Equal Pay Act, and the Massachusetts Minimum Fair Wage Law, as well as any claim or right under your Employment Agreement unless as provided herein.

This waiver, release, and discharge includes any claims arising under any employment agreement you have had with the Company and any amendments thereto.

Massachusetts Wage Act Waiver. By signing this Agreement, you acknowledge that this waiver includes any claims against the Company Releasees under Mass. Gen. Laws ch. 149, § 148 et seq.,—the Massachusetts Wage Act. These claims include, but are not limited to, claims for failure to pay earned wages, failure to pay overtime, failure to pay earned commissions, failure to timely pay wages, failure to pay accrued vacation or holiday pay, failure to furnish appropriate pay stubs, improper wage deductions, and failure to provide proper check-cashing facilities.

(b) Notwithstanding the generality of the foregoing, nothing herein constitutes a release or waiver by you of, or prevents you from making or asserting: (i) any claim or right you may have under COBRA; (ii) any claim or right you may have for unemployment insurance or workers' compensation benefits (other than for retaliation under workers' compensation laws); (iii) any claim to vested benefits under the written terms of a qualified employee pension benefit plan; (iv) any claim for indemnity pursuant to Section 25 of your Employment Agreement, which is incorporated herein by reference; (v) any medical claim incurred during your employment that is payable under applicable medical plans or an employer-insured liability plan; (vi) any claim or right that may arise after the execution of this Agreement; (vii) any claim or right you may have under this Agreement; or (viii) any claim that is not otherwise able to be waived under applicable law.

(c) In addition, nothing herein shall prevent you from filing a charge or complaint with the Equal Employment Opportunity Commission ("EEOC") or similar federal or state fair employment practices agency or interfere with your ability to participate in any investigation or proceeding conducted by such agency; provided, however, that pursuant to Section 3(a), you are waiving any right to recover monetary damages or any other form of personal relief from the Company Releasees to the extent any such charge, complaint, investigation or proceeding asserts a claim subject to the release in Section 3(a) above. To the extent you receive any such personal or monetary relief in connection with any such charge, complaint, investigation or proceeding, the Company will be entitled to an offset for the payment made pursuant to Section 2 of this Agreement.

4. No Additional Entitlements. You agree and represent that other than as provided for in this Agreement, you have received all entitlements due from the Company relating to your employment with the Company or under your Employment Agreement, including but not limited to, all wages earned, including without limitation all commissions and bonuses, sick pay, vacation pay, overtime pay, and any paid and unpaid personal leave for which you were eligible and entitled, and that no other entitlements are due to you other than as set forth in this Agreement. Additionally, the Company agrees not to contest any claim for unemployment benefits you may file; provided, however, that the Company may respond to any inquiry from the unemployment compensation board to the extent you make any

allegations of wrongdoing by the Company. Except as expressly provided for herein, your Employment Agreement with the Company is hereby terminated.

5. Protection of Confidential Information. Except as expressly permitted in Section 7 of this Agreement or if otherwise required by law, you agree that you will not at any time, directly or indirectly, use or disclose any trade secret, confidential or proprietary information you have learned by reason of your employment with the Company and will continue to abide by your confidentiality obligations pursuant to Section 15 of your Employment Agreement.

6. Non-Disparagement. Except as expressly permitted in Section 7 of this Agreement, you agree that you shall not at any time make any written or oral comments or statements of a defamatory or disparaging nature regarding the Company and/or the Company Releasees and you shall not take any action that would cause or contribute to their being held in disrepute. You and the Company agree to prepare a mutually acceptable communication to employees and third parties regarding your separation.

7. Reports to Government Entities. Nothing in this Agreement restricts or prohibits you from initiating communications directly with, responding to any inquiries from, providing testimony before, providing confidential information to, reporting possible violations of law or regulation to, or from filing a claim or assisting with an investigation directly with a self-regulatory authority or a government agency (collectively, the "Regulators"), or from making other disclosures that are protected under the whistleblower provisions of federal, state, or local law or regulation. You do not need the prior authorization of the Company to engage in conduct protected by this Section, and you do not need to notify the Company that you have engaged in such conduct. Please take notice that federal law provides criminal and civil immunity to federal and state claims for trade secret misappropriation to individuals who disclose a trade secret to their attorney, a court, or a government official in certain, confidential circumstances that are set forth at 18 U.S.C. §§ 1833(b)(1) and 1833(b)(2), related to the reporting or investigation of a suspected violation of the law, or in connection with a lawsuit for retaliation for reporting a suspected violation of the law.

8. Non-Admission. It is understood and agreed that neither the execution of this Agreement nor the terms of this Agreement constitute an admission of liability to you by the Company or the Company Releasees, and such liability is expressly denied. It is further understood and agreed that no person shall use the Agreement, or the consideration paid pursuant thereto, as evidence of an admission of liability, inasmuch as such liability is expressly denied.

9. Cooperation. You agree that upon the Company's reasonable notice to you, and a reasonable request, you shall cooperate with the Company and its counsel (including, if necessary, preparation for and appearance at depositions, hearings, trials or other proceedings) with regard to matters that relate to or arise out of matters you have knowledge about or have been involved with during your employment with the Company. In the event that such cooperation is required, you will be reimbursed for any reasonable travel expenses incurred in connection therewith.

10. Confidentiality of the Agreement. Except as permitted in Section 7 of this Agreement, as may be required pursuant to the Securities Exchange Act of 1934, as amended, and the rules and regulations thereof, or if otherwise required by law, the parties, including the Company, shall not disclose the terms of this Agreement, or the circumstances giving rise to this Agreement, to any person other than their respective attorneys, immediate family members, accountants, financial advisors or corporate employees who have a business need to know such terms in order to approve or implement such terms.

11. Continuing Obligations. Subject to Section 7 of this Agreement, you reaffirm and agree that you remain bound by Sections 15-17 of your Employment Agreement, which remain binding and in full force and effect in accordance with its terms, and is incorporated herein by reference.

12. Acknowledgments. You hereby acknowledge that:

(a) The Company advises you to consult with an attorney before signing this Agreement;

(b) You have obtained independent legal advice from an attorney of your own choice with respect to this Agreement, or you have knowingly and voluntarily chosen not to do so;

(c) You freely, voluntarily and knowingly entered into this Agreement after due consideration;

(d) You have had a minimum of twenty-one (21) days to review and consider this Agreement;

(e) You and the Company agree that changes to the Company's offer contained in this Agreement, whether material or immaterial, will not restart the twenty-one (21) day consideration period provided for in Section 12(d) above;

(f) You have a right to revoke this Agreement by notifying the undersigned representative in writing, via hand delivery, facsimile or electronic mail, within seven (7) business days of your execution of this Agreement;

(g) In exchange for your waivers, releases and commitments set forth herein, including your waiver and release of all claims arising under the ADEA, the payments, benefits and other considerations that you are receiving pursuant to this Agreement exceed any payment, benefit or other thing of value to which you would otherwise be entitled, and are just and sufficient consideration for the waivers, releases and commitments set forth herein; and

(h) No promise or inducement has been offered to you, except as expressly set forth herein, and you are not relying upon any such promise or inducement in entering into this Agreement.

13. Medicare Disclaimer. You acknowledge that you are not a Medicare Beneficiary as of the time you enter into this Agreement. To the extent that you are a Medicare Beneficiary, you agree to contact a Company Human Resources Representative for further instruction.

14. Miscellaneous.

(a) Entire Agreement. This Agreement, together with the expressly incorporated provisions of your Employment Agreement and the Consulting Agreement, sets forth the entire agreement between you and the Company and replaces any other oral or written agreement between you and the Company relating to the subject matter of this Agreement, including, without limitation, any prior offer letters and/or employment agreements.

(b) Governing Law. This Agreement shall be construed, performed, enforced and in all respects governed in accordance with the laws of the Commonwealth of Massachusetts, without giving effect to the principles of conflicts of law thereof. Additionally, all disputes arising from or related to this Agreement shall be brought in a state or federal court situated in the Commonwealth of Massachusetts, Suffolk County, and the parties hereby expressly consent to the jurisdiction of such courts for all purposes related to resolving such disputes.

(c) Severability. Should any provision of this Agreement be held to be void or unenforceable, the remaining provisions shall remain in full force and effect, to be read and construed as if the void or unenforceable provisions were originally deleted.

(d) Amendments. This Agreement may not be modified or amended, except upon the express written consent of both you and the Company.

(e) Breach. You acknowledge that if you breach your commitments to the Company agreed upon in Sections 5, 6, 8, 9, 10 or 11 you will forfeit the severance benefits set forth in Section 2 and be subject to suit by the Company for damages and equitable relief relating to such breach and your Consulting Agreement will terminate immediately. You further acknowledge that any breach by you of Sections 5, 6, , 8, 9, 10 and 11 will cause irreparable damage to the Company and that in the event of such breach the Company shall have, in addition to any and all remedies at law, the right to an injunction, specific performance or other equitable relief to prevent the violation of your obligations hereunder.

(f) Waiver. A waiver by either party hereto of a breach of any term or provision of the Agreement shall not be construed as a waiver of any subsequent breach.

(g) Counterparts. This Agreement may be executed in one or more counterparts, and be transmitted by facsimile or pdf, each of which shall be deemed an original, but all of which together shall constitute one and the same agreement.

(h) Effective Date. This Agreement will become effective and enforceable upon the expiration of the seven (7) business day revocation period provided for in Section 13(f) above (the "Effective Date"). If you fail to return an executed original by April 20, 2020 (or otherwise revoke this Agreement pursuant to Section 13(f) above), this Agreement, including but not limited to the obligation of the Company to provide the compensation and benefits provided in Section 2 above, shall be deemed automatically null and void.

[Signature Page Follows]

If the above accurately states our agreement, including the separation, waiver and release, kindly sign below and return the original Agreement to me no earlier than March 31, 2020 and by no later than April 20, 2020.

Sincerely,

Replimune Inc.

By: /s/ Jean Franchi

Date: April 3, 2020

UNDERSTOOD, AGREED TO AND ACCEPTED WITH THE INTENTION TO BE LEGALLY BOUND:

/s/ Steven Gorgol
Stephen Gorgol

Date: April 2, 2020

Signature Page to Separation and Release Agreement

EXHIBIT A

EMPLOYMENT AGREEMENT

[Attached.]

EXHIBIT B

REPLIMUNE, INC.

CONSULTING AGREEMENT

This CONSULTING AGREEMENT (this "Agreement") is dated as of March 31, 2020, by and between Replimune, Inc. (the "Company") and Stephen Gorgol (the "Consultant"). This Agreement will be effective on the first business day following the Effective Date (as defined in that certain Separation Agreement and Release, dated of March 30, 2020, between the Company and the Consultant (the "Separation Agreement")). For the avoidance of doubt, if the Consultant does not execute or revokes the Separation Agreement, this Agreement shall not become effective, the Term (as defined in Section 3(a) below) of this Agreement shall not commence and this Agreement shall automatically terminate and become null and void ab initio.

1. Consulting Services.

(a) Subject to and upon the terms and conditions set forth in this Agreement, effective on the first business day following the Effective Date (the "Start Date"), the Company hereby retains the Consultant, and the Consultant hereby agrees to be retained by the Company, to provide consulting services including transition support, completion of year-end requirements, completion of special projects and such other services as shall be determined and reasonably requested from time to time by the Chief Financial Officer of the Company (the "Services").

(b) The amount of time that Consultant shall devote to the performance of the Services pursuant to this Agreement shall be mutually agreed upon by the Consultant and the Company, but is expected to be sufficient to successfully complete the Services and will likely decrease over the Term.

(c) The Consultant shall provide the Services under this Agreement at such times and locations as are mutually agreed upon by the Consultant and the Company. In rendering the Services under this Agreement, the Consultant shall act solely as an independent contractor, the Consultant will not eligible for any employee benefit plans or programs maintained by the Company, and this Agreement shall not be construed to create any employee/employer relationship between the Consultant and the Company.

(d) During the Term of this Agreement, and except to the extent otherwise agreed upon in writing by the Consultant and the Company, the Consultant will keep separate and not co-mingle (i) his Services for the Company, and (ii) any contact information obtained during his consulting relationship with the Company, with those provided, or pursuant, to any other consulting arrangements.

(e) It is understood and agreed that, subject to Sections 15-17 of that certain Employment Agreement by and between the Consultant and the Company, dated May 8, 2019 (the "Employment Agreement"), the Consultant may be involved in any capacity in other businesses, endeavors and undertakings. The Consultant agrees that his continuing obligations under Sections 15-17 of the Employment Agreement shall remain in full force and effect during the Term of this Agreement and are hereby incorporated by reference, *provided, that*, solely for purposes of this

Section 1(e), the terms of the Employment Agreement are hereby modified such that reference therein to the term of the Consultant's employment with the Company and termination thereof shall include reference to the Consultant's consultancy pursuant to this Agreement and the termination thereof such that, for example, the non-solicitation and non-competition covenants set forth in the Employment Agreement shall continue during the Term of this Agreement and for the one-year period thereafter. As consideration for the payments, continued vesting of the Options (as defined in Section 2(e) below) and extension of the exercise period of the Options, if applicable, the Consultant agrees to continue to abide by the terms of the Employment Agreement as modified pursuant to the foregoing provisions of this Section 1(e).

2. Compensation and Options.

(a) Subject to, and in accordance with, the terms and conditions set forth in this Agreement, during the Initial Term (as defined in Section 3(a) below), the Consultant will be eligible for the following cash payments:

(i) A consulting fee in an amount equal to $27,100 per month (the "Consulting Fee"). Such Consulting Fee shall be paid in monthly installments on the last business day of each calendar month. For the avoidance of doubt, nothing in this Agreement shall entitle the Consultant to the Consulting Fee after the end of the Term, even if the Term ends during the Initial Term.

(ii) Two payments, subject to the attainment of certain milestones, as determined by the Chief Financial Officer in her sole discretion ("Milestone Payments"). Provided that the Company's 2019 audited financials are timely and accurately completed no later than June 12, 2020, and without material adjustments or other weakness disclosures by the Company's independent accounting firm, as determined by the Chief Financial Officer in her sole discretion, the Company shall pay the Consultant the first Milestone Payment in the amount of $50,000, on or around June 30, 2020, subject to the Consultant's continuing to provide the Services on the payment date. Upon the successful completion of the Services at the end of the Initial Term, as determined by the Chief Financial Officer in her sole discretion, the Company shall pay the Consultant the second Milestone Payment in the amount of $40,000 on or around December 31, 2020, but no later than January 30, 2021, subject to the Consultant's continuing the Services through December 31, 2020.

(b) Subject to, and in accordance with, the terms and conditions set forth in this Agreement, during any Renewal Period (as defined in Section 3(b) below), the Company shall pay the Consultant an hourly consulting fee in an amount equal to $175 per hour (the "Consulting Hourly Fee"). Such Consulting Hourly Fee shall be paid within 30 days following the Consultant's submission to the Company of a monthly invoice.

(c) The Company will not withhold any income or other employment taxes from the payments due to the Consultant under this Agreement. The Consultant hereby agrees that he will timely pay all taxes and fees upon the income paid by the Company hereunder, and will indemnify and hold the Company harmless against the claims of any governmental taxing authority made in connection with the revenue derived by the Consultant under this Agreement.

(d) The Company shall reimburse the Consultant for any actual out-of-pocket expenses incurred by the Consultant while rendering Services under this Agreement so long as such expenses are reasonable and necessary, and appropriately documented and approved per the Company's standard practices. Without limiting the generality of the foregoing, any out-of-pocket travel expenses as well as any out-of-pocket expenses that, individually or in the aggregate, exceed $500.00, shall be reimbursed by the Company only if approved by the Company in advance of such out-of-pocket expenses being incurred by the Consultant.

(e) All of the Consultant's stock options to purchase shares of Replimune Group, Inc.'s common stock ("Options") that are unvested as of the Last Day of Employment (as defined in the Separation Agreement) will continue to vest in accordance with the terms of the governing plan and award agreements ("Award Agreements"), until the earlier of: (i) the termination of this Agreement for any reason or no reason in accordance with Section 3 below and (ii) December 31, 2020.

(f) Subject to this Section 2(f), notwithstanding the terms of the Award Agreements, if the Consultant continues to provide Services under this Agreement through December 31, 2020, all Options to the extent then vested and exercisable (regardless of whether such Options become vested and exercisable pursuant to Section 2(e) above) will remain exercisable for one year following the end of the Term; provided, that, nothing in this Section 2(f) shall permit any Option to be exercised following the expiration of applicable Option term, as provided in the governing plan document and/or Award Agreements. Any Options that are unvested as of December 31, 2020 shall automatically and without any further action be forfeited with no further consideration.

(g) Except for the Consulting Fee and, if applicable, the Consulting Hourly Fee, any expense reimbursement made in accordance with Section 2(d) hereof, any Milestone Payments made in accordance with Section 2(b)(ii) hereof, and any Option vesting arrangement set forth in Section 2(e) or Option extension set forth in 2(f) hereof, the Company shall have no obligation to provide any compensation or benefits to the Consultant with respect to any Services rendered by the Consultant to the Company pursuant to this Agreement.

3. Term; Termination.

(a) This Agreement shall take effect as of the Start Date and shall continue thereafter in full force and effect until December 31, 2020 (the "Initial Term"), unless extended in accordance with the provisions of Section 3(b) hereof, or terminated in accordance with the provisions of Section 3(c) hereof (the "Term"). The Consultant shall begin providing the Services to the Company on the Start Date.

(b) On and after January 1, 2021, this Agreement may be renewed by the Company for successive one-month periods (the "Renewal Period(s)") if the Company gives the Consultant at least 14 days' prior written notice of such renewal and the Renewal Period is agreed to by the Consultant and the Company in writing. All references to the "Term" in this Agreement shall be deemed to include all Renewal Periods, if any. If the Agreement is extended under a Renewal Period, the only compensation for the Consultant's services during the Renewal Period shall be the Consulting Hourly Fee, as set forth in Section 2(b) hereof.

(c) This Agreement and the Services provided by the Consultant hereunder may be terminated at any time by either the Consultant or the Company for any reason or no reason by giving at least 30 days' prior written notice of termination to the other party; *provided, that*, the Company may terminate this Agreement without prior notice upon a determination that the Consultant has not performed the Services provided for hereunder to its reasonable satisfaction, as determined by the Chief Financial Officer in her sole discretion, or Consultant has engaged in any misconduct that has the effect, or potential effect, of causing harm to the Company (monetarily, reputationally or otherwise). This Agreement and the Services provided by the Consultant hereunder shall terminate immediately upon the Consultant's death. Upon termination of this Agreement and the Services for any reason, the Company is only obligated to pay the Consultant any amounts owed for the Services performed through the date of termination. The provisions of Sections 1(e), 2(c), 3(d), 4, 5, 6 and 7 of this Agreement and the provisions of Sections 15-17 of the Employment Agreement, as modified by the provisions of Section 1(e), shall survive the termination of this Agreement.

(d) Upon expiration or termination of this Agreement, the Consultant agrees that he will not represent himself to third parties as continuing to have ongoing obligations to and with the Company, and will not hold himself out as having a role with the Company, nor have any authority to speak or act for or on behalf of the Company.

4. No Conflicting Obligation. The Consultant hereby represents that he is free to enter into this Agreement and that his performance of all of the terms of this Agreement and of all of his duties as a consultant to the Company do not and will not breach (i) any agreement to keep in confidence information acquired by the Consultant in confidence or in trust, (ii) any agreement to assign to any third party inventions made by the Consultant, or (iii) any agreement not to compete against the business of any third party. Consultant further represents that he has not made and will not make any agreements in conflict with this Agreement.

5. No Use of Name, Etc.

(a) Without the prior written consent of the Company, the Consultant shall not at any time use, for himself or on behalf of any other person, any name that is identical or similar to or likely to be confused with the name of the Company or any of Affiliate of the Company (as defined in Section 7(c) below) or any product or service produced or provided by the Company or any Affiliate of the Company.

(b) The Consultant shall not hold himself out as currently representing the Company without the prior written consent of the Company, unless it is within the scope of the Services being provided for the Company. Matters and inquiries outside the scope of the Services and relating to the Company should be directed to the Chief Executive Officer of the Company.

(c) Nothing in this Agreement restricts or prohibits the Consultant from initiating communications directly with, responding to any inquiries from, providing testimony before, providing confidential information to, reporting possible violations of law or regulation to, or from filing a claim or assisting with an investigation directly with a self-regulatory authority or a government agency, or from making other disclosures that are protected under the whistleblower

provisions of federal, state, or local law or regulation. The Consultant does not need the prior authorization of the Company to engage in conduct protected by this Section, and the Consultant does not need to notify the Company that he has engaged in such conduct. The Consultant should take notice that federal law provides criminal and civil immunity to federal and state claims for trade secret misappropriation to individuals who disclose a trade secret to their attorney, a court, or a government official in certain, confidential circumstances that are set forth at 18 U.S.C. §§ 1833(b)(1) and 1833(b)(2), related to the reporting or investigation of a suspected violation of the law, or in connection with a lawsuit for retaliation for reporting a suspected violation of the law.

6. Return of Property. The Consultant agrees to promptly return to the Company after the end of the Term or sooner if requested by Company all of its property, including, but not limited to, computers, files, and documents, including any correspondence or other materials containing trade secrets of the Company, identification cards, credit cards, keys, equipment, software and data, however stored other an as required to perform the consultancy services, as agreed with the Company. To the extent the Consultant has any Company information or material stored on any PDA, personal computer, personal email, hard drive, thumb drive, cloud or other electronic storage device, the Consultant agrees to cooperate with the Company in permanently deleting such information from such devices, subject to any Company litigation preservation directive then in effect.

7. Miscellaneous.

(a) This Agreement represents the entire Agreement of the parties with respect to the arrangements contemplated hereby. No prior agreement, whether written or oral, shall be construed to change, amend, alter, repeal or invalidate this Agreement. This Agreement may be amended only by a written instrument executed in one or more counterparts by the parties.

(b) No consent to or waiver of any breach or default in the performance of any obligations hereunder shall be deemed or construed to be a consent to or waiver of any other breach or default in the performance of any of the same or any other obligations hereunder. Failure on the part of either party to complain of any act or failure to act of the other party or to declare the other party in default, irrespective of the duration of such failure, shall not constitute a waiver of rights hereunder and no waiver hereunder shall be effective unless it is in writing, executed by the party waiving the breach or default hereunder.

(c) This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and permitted assigns. This Agreement may be assigned by the Company to any Affiliate of the Company (as long as the Company remains secondarily liable for any payments or obligations hereunder) and to a successor of its business to which this Agreement relates (whether by purchase or otherwise). "Affiliate of the Company" means any person or entity which, directly or indirectly, controls or is controlled by or is under common control with the Company and, for the purposes of this definition, "control" (including the terms "controlled by" and "under common control with") shall mean the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of another whether through the ownership of voting securities or holding of office in another, by contract or otherwise. The Consultant may not assign or transfer any or all of his rights or obligations under this Agreement;

provided, that, any amounts due under this Agreement upon or following the Consultant's death shall be paid to Consultant's estate or beneficiaries, as applicable.

(d) Unless otherwise provided herein, any notice, report, payment or document to be given by one party to the other shall be in writing and shall be deemed given when delivered personally or mailed by certified or registered mail, postage prepaid (such mailed notice to be effective on the date which is three (3) business days after the date of mailing), or sent by nationally recognized overnight courier (such notice sent by courier to be effective one business day after it is deposited with such courier), or sent by email (such notice sent by email to be effective when sent, if confirmed by certified or registered mail or overnight courier as aforesaid), or sent by telefax (such notice sent by telefax to be effective when sent, if confirmed by certified or registered mail or overnight courier as aforesaid) addressed to the party at the address set forth on the signature page to this Agreement or to such other place as any party may designate as to itself by written notice to the other party. Either party may change its address for notices by means of a notice delivered in accordance with this Section 7(d). Notwithstanding the foregoing, all such notices, reports, payments or documents provided by the Company to the Consultant shall be sent by email (in addition to any other form of delivery chosen by the Company) to the Consultant at his personal email address on file with the Company.

(e) This Agreement shall be governed by and construed in accordance with the substantive laws of the Commonwealth of Massachusetts without reference to any choice or conflict of laws rule or provision that would result in the application of the substantive law of any other jurisdiction. Section headings of this Agreement are for reference only and shall not affect its interpretation. In the event that any provision of this Agreement should be held unenforceable by a court of competent jurisdiction, such court is hereby authorized to amend such provision so as to be enforceable to the fullest extent permitted by law, and all remaining provisions shall continue in full force without being impaired or invalidated in any way.

(f) The parties agree that any breach or threatened breach of Sections 1(e), 4, 5, 6 or 7 of this Agreement by the Consultant may cause irreparable harm to the Company; and that money damages will not provide an adequate remedy. In the event of a breach or threatened breach of Sections 1(e), 4, 5, 6 or 7 of this Agreement by the Consultant, the Company shall, in addition to any other rights and remedies it may have, be entitled to seek an injunction, without the need to post bond.

(g) This Agreement may be executed in counterparts, all of which together shall for all purposes constitute one agreement binding on each of the parties hereto notwithstanding that each such party shall not have signed the same counterpart.

[*Signature Page Follows*]

IN WITNESS WHEREOF, the parties have signed this Agreement as of the date first above written, intending it to take effect as a sealed instrument.

REPLIMUNE, INC.

By: _____
Name:
Title:
Address:
Email:

CONSULTANT

By: _____
Stephen Gorgol

Address:

Email:

Signature Page to the Consulting Agreement

Exhibit 10.21

FIRST AMENDMENT TO LOAN AND SECURITY AGREEMENT

THIS FIRST AMENDMENT TO LOAN AND SECURITY AGREEMENT (this "Amendment"), dated as of June 1, 2020 (the "Amendment Effective Date"), is entered into by and among REPLIMUNE GROUP, INC., a Delaware corporation, and each of its Subsidiaries (other than Excluded Subsidiaries and the MSC Subsidiary) (individually and collectively, "Borrower"), the several banks and other financial institutions or entities from time to time parties to the Loan Agreement (as defined below) (collectively, the "Lenders"), and HERCULES CAPITAL, INC., a Maryland corporation, in its capacity as administrative agent and collateral agent (in such capacity, "Agent").

Borrower, Lender and Agent are parties to that certain Loan and Security Agreement, dated as of August 7, 2019 (the "Existing Loan Agreement"; and the Existing Loan Agreement, as amended by this Amendment and as further amended, restated, supplemented or otherwise modified from time to time, the "Loan Agreement"). Borrower has requested that Agent and Lenders agree to certain amendments to the Existing Loan Agreement. Agent and Lenders have agreed to such request, subject to the terms and conditions hereof.

Accordingly, the parties hereto agree as follows:

SECTION 1 Definitions; Interpretation.

(a) **Terms Defined in Loan Agreement**. All capitalized terms used in this Amendment (including in the recitals hereof) and not otherwise defined herein shall have the meanings assigned to them in the Loan Agreement.

(b) **Rules of Construction**. The rules of construction that appear in Section 1.3 of the Loan Agreement shall be applicable to this Amendment and are incorporated herein by this reference.

SECTION 2 Amendments to the Loan Agreement. The Loan Agreement shall be amended as follows effective as of the Amendment Effective Date:

(a) Recitals. Recital A is hereby amended and restated in its entirety as follows:

"Borrower has requested the Lenders make available to Borrower term loans in an aggregate principal amount of up to Forty Million Dollars ($40,000,000) (collectively, the "Term Loan"); and"

(b) Section 1.1 (New Definition). The following definition is added to Section 1.1 in its proper alphabetical order:

"Draw Milestone" means receipt by Agent, at the time of a request to draw the Tranche 4 Advance, of evidence satisfactory to Agent that Borrower has either (i) two ongoing registration-directed clinical studies in two distinct clinical indications, or (ii) one ongoing registration-directed clinical study and data from a completed registration-enabling clinical study in a distinct indication, in each case, which Lender determines in its reasonable discretion, supports a Biologics License Application filing as the next immediate developmental step.

(c) Section 1.1 (Amended and Restated Definitions). The following definitions are hereby amended and restated as follows:

"Amortization Date" means September 1, 2022.

"Maximum Term Loan Amount" means Forty Million and No/100 Dollars ($40,000,000).

"Term Loan Advance" means each Tranche 1 Advance, Tranche 2 Advance, Tranche 3 Advance, Tranche 4 Advance and any other Term Loan funds advanced under this Agreement."

(d) Section 1.2 (Defined Terms). The following defined term is added to Section 1.2 in its proper alphabetical order:

"Tranche 4 Advance 2.2(a)"

(e) Section 2.2. Clause (a) of Section 2.2 is hereby amended and restated in its entirety as follows:

"(a) Advances. The Lenders severally (and not jointly) made a Term Loan Advance of Ten Million Dollars ($10,000,000) to Borrower on the Closing Date (the "Tranche 1 Advance"). Subject to the terms and conditions of this Agreement, beginning on October 1, 2020, and continuing through December 15, 2020, Borrower may request and the Lenders shall severally (and not jointly) make an additional Term Loan Advance in a principal amount of Ten Million Dollars ($10,000,000) (the "Tranche 2 Advance"). Subject to the terms and conditions of this Agreement, beginning on July 1, 2020, and continuing through June 30, 2021, Borrower may request and the Lenders shall severally (and not jointly) make an additional Term Loan Advance in a principal amount of Ten Million Dollars ($10,000,000) (the "Tranche 3 Advance"). Subject to the terms and conditions of this Agreement, beginning on July 1, 2021, and continuing through December 15, 2021, and subject to Borrower's achievement of the Draw Milestone, Borrower may request and the Lenders shall severally (and not jointly) make an additional Term Loan Advance in a principal amount of Ten Million Dollars ($10,000,000) (the "Tranche 4 Advance"). Notwithstanding the foregoing, subject to the terms and conditions of this Agreement, and conditioned on approval by the Lenders' investment committee in its sole discretion, any of the Tranche 2 Advance or Tranche 3 Advance may be drawn prior to the draw periods set forth above if such Advance is made to support corporate strategic initiatives of Borrower. The aggregate outstanding Term Loan Advances may be up to the Maximum Term Loan Amount.

(f) Section 2.10. A new Section 2.10 is added after Section 2.9 to read as follows:

"2.10 Tranche 2 Unused Fee. In the event that Borrower (a) does not draw a Tranche 2 Advance or (b) this Agreement is terminated prior to a draw of the Tranche 2 Advance, Borrower shall pay to the Lenders, in the aggregate, a fee of One Hundred Thousand Dollars ($100,000) (the "Tranche 2 Unused Fee") on the earliest to occur of (i) December 16, 2020, or (ii) the date that Borrower prepays the outstanding Secured Obligations (other than any inchoate indemnity obligations and any other obligations which, by their terms, are to survive the termination of this Agreement) in full.

(g) Schedule 1.1. Schedule 1.1 of the Loan Agreement is hereby amended and restated in its entirety with the attached Schedule 1.1.

(h) **References Within Existing Loan Agreement**. Each reference in the Existing Loan Agreement to "this Agreement" and the words "hereof," "herein," "hereunder," or words of like import, shall mean and be a reference to the Existing Loan Agreement as amended by this Amendment.

SECTION 3 Conditions of Effectiveness. The effectiveness of Section 2 of this Amendment shall be subject to the satisfaction of each of the following conditions precedent:

(a) Agent shall have received:

(i) this Amendment, executed by Agent, Lenders and Borrower;

(ii) a facility charge of One Hundred Thousand Dollars ($100,000),

(iii) a perfection certificate (the "Perfection Certificate"), executed by Borrower, in form and substance reasonably satisfactory to Agent;

(iv) certified copy of resolutions of Borrower's board of directors evidencing approval of this Amendment and other transactions evidenced hereby;

(v) a certificate of good standing for Borrower from its state of incorporation and similar certificates from all other jurisdictions in which it does business and where the failure to be qualified could have a Material Adverse Effect; and

(vi) such other documents as Agent may reasonably request.

(b) On the Amendment Effective Date, after giving effect to the amendment of the Existing Loan Agreement contemplated hereby, (i) the representations and warranties contained in Section 4 shall be true and correct on and as of the Amendment Effective Date as though made on and as of such date; and (ii) there exist no Events of Default or events that with the passage of time would result in an Event of Default.

SECTION 4 Representations and Warranties. To induce Agent and Lenders to enter into this Amendment, Borrower hereby confirms, as of the Amendment Effective Date, that (a) the representations and warranties made by it in Section 5 of the Loan Agreement and in the other Loan Documents are true and correct in all material respects; *provided*, *however*, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof provided, further, that to the extent such representations and warranties by their terms expressly relate only to a prior date such representations and warranties shall be true and correct as of such prior date; (b) there has not been and there does not exist a Material Adverse Effect; (c) that the information included in the Perfection Certificate delivered to Agent on the Amendment Effective Date is true and correct; (d) the agreements and obligations of Borrower contained in the Loan Documents and in this Amendment constitute the legal, valid and binding obligations of Borrower, enforceable against Borrower in accordance with their respective terms, except as the enforceability thereof may be limited by bankruptcy, insolvency or other similar laws of general application affecting the enforcement of creditors' rights or by the application of general principles of equity; (e) the execution, delivery and performance of this Amendment by Borrower (i) will not result in the creation or imposition of any Lien upon the Collateral, (ii) do not violate any provisions of Borrower's constitutional or governing documents, (iii) do not violate any material law, regulation, order, injunction, judgment, decree or writ to which Borrower is subject and (iv) do not violate any material contract or agreement or require the consent or approval of any other Person which has not already been obtained; and (f) no Event of Default has occurred and is continuing.

SECTION 5 Miscellaneous.

(a) **Performance Milestone**. Agent and Lenders acknowledge that Borrower has achieved the Performance Milestone as of the Amendment Effective Date.

(b) **Loan Documents Otherwise Not Affected; Reaffirmation; No Novation.**

(i) Except as expressly amended pursuant hereto or referenced herein, the Existing Loan Agreement and the other Loan Documents shall remain unchanged and in full force and effect and are hereby ratified and confirmed in all respects. Lenders' and Agent's execution and delivery of, or acceptance of, this Amendment shall not be deemed to create a course of dealing or otherwise create any express or implied duty by any of them to provide any other or further amendments, consents or waivers in the future.

(ii) Borrower hereby expressly (1) reaffirms, ratifies and confirms its Secured Obligations under the Existing Loan Agreement and the other Loan Documents, (2) reaffirms, ratifies and confirms the grant of security under Section 3.1 of the Existing Loan Agreement, (3) reaffirms that such grant of security in the Collateral secures all Secured Obligations under the Existing Loan Agreement, including without limitation any Term Loans funded on or after the date hereof, as of the date hereof, and with effect from (and including) the date hereof, such grant of security in the Collateral: (x) remains in full force and effect notwithstanding the amendments expressly referenced herein; and (y) secures all Secured Obligations under the Existing Loan Agreement, as amended by this Amendment, and the other Loan Documents, and (4) agrees that the Existing Loan Agreement and each other Loan Document shall remain in full force and effect following any action contemplated in connection herewith.

(iii) This Amendment is not a novation and the terms and conditions of this Amendment shall be in addition to and supplemental to all terms and conditions set forth in the Loan Documents. Nothing in this

Amendment is intended, or shall be construed, to constitute an accord and satisfaction of Borrower's Secured Obligations under or in connection with the Existing Loan Agreement and any other Loan Document or to modify, affect or impair the perfection or continuity of Agent's security interest in, (on behalf of itself and Lenders) security titles to or other liens on any Collateral for the Secured Obligations.

(c) **Conditions**. For purposes of determining compliance with the conditions specified in Section 3, Lenders that have signed this Amendment shall be deemed to have consented to, approved or accepted or to be satisfied with, each document or other matter required thereunder to be consented to or approved by or acceptable or satisfactory to Lenders unless Agent shall have received notice from Lenders prior to the Amendment Effective Date specifying its objection thereto.

(d) **Release**. In consideration of the agreements of Agent and Lenders contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Borrower, on behalf of itself and its successors, assigns, and other legal representatives, hereby fully, absolutely, unconditionally and irrevocably releases, remises and forever discharges Agent and Lenders, and its successors and assigns, and its present and former shareholders, affiliates, subsidiaries, divisions, predecessors, directors, officers, attorneys, employees, agents and other representatives (Agent, Lenders and all such other persons being hereinafter referred to collectively as the "Releasees" and individually as a "Releasee"), of and from all demands, actions, causes of action, suits, covenants, contracts, controversies, agreements, promises, sums of money, accounts, bills, reckonings, damages and any and all other claims, counterclaims, defenses, rights of set-off, demands and liabilities whatsoever of every name and nature, known or unknown, suspected or unsuspected, both at law and in equity, which Borrower, or any of its successors, assigns, or other legal representatives may now or hereafter own, hold, have or claim to have against the Releasees or any of them for, upon, or by reason of any circumstance, action, cause or thing whatsoever which arises at any time on or prior to the day and date of this Amendment for or on account of, or in relation to, or in any way in connection with the Loan Agreement, or any of the other Loan Documents or the transactions thereunder or related thereto. Borrower waives the provisions of California Civil Code section 1542, which states:

> A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS THAT THE CREDITOR OR RELEASING PARTY DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE AND THAT, IF KNOWN BY HIM OR HER, WOULD HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR OR RELEASED PARTY.

Borrower understands, acknowledges and agrees that the release set forth above may be pleaded as a full and complete defense and may be used as a basis for an injunction against any action, suit or other proceeding which may be instituted, prosecuted or attempted in breach of the provisions of such release. Borrower agrees that no fact, event, circumstance, evidence or transaction which could now be asserted or which may hereafter be discovered shall affect in any manner the final, absolute and unconditional nature of the release set forth above. The provisions of this section shall survive payment in full of the Secured Obligations, full performance of all the terms of this Amendment and the other Loan Documents.

(e) **No Reliance**. Borrower hereby acknowledges and confirms to Agent and Lenders that such Borrower is executing this Amendment on the basis of its own investigation and for its own reasons without reliance upon any agreement, representation, understanding or communication by or on behalf of any other Person.

(f) **Costs and Expenses**. Borrower agrees to pay to Agent on the Amendment Effective Date the reasonable and documented out-of-pocket costs and expenses of Agent and Lenders party hereto, and the reasonable and documented fees and disbursements of counsel to Agent and Lenders party hereto in connection with the negotiation, preparation, execution and delivery of this Amendment and any other documents to be delivered in connection herewith on the Amendment Effective Date.

(g) **Binding Effect**. This Amendment binds and is for the benefit of the successors and permitted assigns of each party.

(h) **Governing Law.** This Amendment and the other Loan Documents shall be governed by, and construed and enforced in accordance with, the laws of the State of California, excluding conflict of laws principles that would cause the application of laws of any other jurisdiction.

(i) **Complete Agreement; Amendments**. This Amendment and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements with respect to such subject matter. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Amendment and the Loan Documents merge into this Amendment and the Loan Documents.

(j) **Severability of Provisions.** Each provision of this Amendment is severable from every other provision in determining the enforceability of any provision.

(k) **Counterparts**. This Amendment may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Amendment. Delivery of an executed counterpart of a signature page of this Amendment by facsimile, portable document format (.pdf) or other electronic transmission will be as effective as delivery of a manually executed counterpart hereof.

(l) **Loan Documents**. This Amendment and the documents related thereto shall constitute Loan Documents.

(m) **Electronic Execution of Certain Other Documents**. The words “execution,” “execute”, “signed,” “signature,” and words of like import in or related to any document to be signed in connection with this Amendment and the transactions contemplated hereby (including without limitation assignments, assumptions, amendments, waivers and consents) shall be deemed to include electronic signatures, the electronic matching of assignment terms and contract formations on electronic platforms approved by Agent, or the keeping of records in electronic form, each of which shall be of the same legal effect, validity or enforceability as a manually executed signature or the use of a paper-based recordkeeping system, as the case may be, to the extent and as provided for in any applicable law, including the Federal Electronic Signatures in Global and National Commerce Act, the California Uniform Electronic Transaction Act, or any other similar state laws based on the Uniform Electronic Transactions Act.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, the parties hereto have duly executed this Amendment, as of the date first above written.

BORROWER:

REPLIMUNE GROUP, INC.

Signature: /s/ Philip Astley-Sparke

Print Name: Philip Astley-Sparke

Title: Chief Executive Officer

REPLIMUNE, INC.

Signature: /s/ Philip Astley-Sparke

Print Name: Philip Astley-Sparke

Title: Treasurer and Secretary

REPLIMUNE LIMITED

Signature: /s/ Philip Astley-Sparke

Print Name: Philip Astley-Sparke

Title: Director

[SIGNATURES CONTINUE ON THE NEXT PAGE]

AGENT:

HERCULES CAPITAL, INC.

Signature: /s/Jennifer Choe

Print Name: Jennifer Choe

Title: Associate General Counsel

LENDERS:

HERCULES CAPITAL, INC.

Signature: /s/Jennifer Choe

Print Name: Jennifer Choe

Title: Associate General Counsel

HERCULES CAPITAL FUNDING TRUST 2019-1

Signature: /s/Jennifer Choe

Print Name: Jennifer Choe

Title: Associate General Counsel

SCHEDULE 1.1

COMMITMENTS

LENDERS	TRANCHE	TERM COMMITMENT	Treaty Passport scheme reference number and jurisdiction of tax residence (if applicable)
Hercules Capital Funding Trust 2019-1	Tranche 1	$ 10,000,000	13/H/376642/DTTP USA
Hercules Capital, Inc.	Tranche 2	$ 10,000,000	13/H/370777/DTTP USA
Hercules Capital, Inc.	Tranche 3	$ 10,000,000	13/H/370777/DTTP USA
Hercules Capital, Inc.	Tranche 4	$ 10,000,000	13/H/370777/DTTP USA
TOTAL COMMITMENTS		$ 40,000,000	

EXHIBIT 10.22

Information in this exhibit identified by [***] is confidential and has been excluded pursuant to Item 601(b)(10)(iv) of Regulation S-K because it is both not material and would likely cause competitive harm to the registrant if publicly disclosed.

EXECUTION COPY

CLINICAL TRIAL COLLABORATION AND SUPPLY AGREEMENT (RP-2)

This **CLINICAL TRIAL COLLABORATION AND SUPPLY AGREEMENT (RP-2)** (the "***Agreement***") is made and entered into effective as of the date signed by the last Party to sign below (the "***Effective Date***") by and between **Replimune Inc.**, a corporation organized under the laws of Delaware, having a place of business at 18 Commerce Way, Woburn, MA 01801 (the "***Recipient***") and **Bristol-Myers Squibb Company**, having a place of business at 345 Park Avenue, New York, NY 10154 ("***BMS***"). The Recipient and BMS are sometimes individually referred to in this Agreement as a "***Party***" and collectively as the "***Parties***."

PRELIMINARY STATEMENTS

A. The Recipient and BMS are parties to that certain Clinical Trial Collaboration and Supply Agreement, made and entered into effective as of February 26, 2018 (the "***RP-1 Agreement***"), pursuant to which Recipient is conducting, and BMS is supplying Opdivo® (nivolumab) for the conduct of, a combined therapy clinical trial of Opdivo® (nivolumab) with Recipient's proprietary oncolytic virus known as RP-1.

B. The Recipient desires to conduct, and BMS desires to supply the BMS Study Drug (as defined below) for the conduct of, a Combined Therapy Clinical Trial (as defined below) in accordance with the Protocol (as defined below) therefor and in accordance with the terms of this Agreement.

C. The Parties desire to agree on various terms and conditions to govern the Parties' obligations in connection with the performance of the Combined Therapy Clinical Trial.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual promises and covenants contained herein, the Parties agree as follows:

ARTICLE 1
DEFINITIONS

The terms in this Agreement with initial letters capitalized, whether used in the singular or the plural, shall have the meaning set forth below or, if not listed below, the meaning designated in places throughout this Agreement.

"***Adverse Event***," ("AE") "***Serious Adverse Event***" ("SAE") and "***Serious Adverse Drug Reaction***" ("SADR") shall have the meanings provided to such terms in the International Conference on Harmonization ("ICH") guideline for industry on Clinical Safety Data Management (E2A, Definitions and Standards for Expedited Reporting).

"***Affiliates***" means, with respect to a particular Party, an entity that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with such Party, only for so long as such control exists. As used in this definition, the term "controls" (with correlative meanings for the terms "controlled by" or "under common control with") means (a) that an entity or company owns, directly or indirectly, more than fifty percent (50%) of the voting stock of another entity, or (b) that an entity, person or group otherwise has the actual ability to control and direct the management of the entity, whether by contract or otherwise.

"***Agreement***" shall have the meaning set forth in the preamble to this Agreement, and includes the Appendices attached hereto, the Supply and Quality Documentation and any and all amendments of any of the foregoing hereafter signed by the Parties with reference to this Agreement and made part hereof.

"***Applicable Law***" means all applicable laws, rules and regulations (whether federal, state or local) that may be in effect from time to time, including current Good Clinical Practices (GCP), Good Laboratory Practices (GLP) and Good Manufacturing Practices (GMP).

"***Arbitration Matter***" means any disputed matter that relates to or arises out of the validity, interpretation or construction of, or the compliance with or breach of, this Agreement; *provided that* such disputed matter has been considered, but not resolved, by the Executive Officers as set forth in Section 13.3. For clarity, no Publication Dispute, or any matter requiring mutual agreement of both Parties shall be an Arbitration Matter.

"***BMS Class Drug***" means (i) the BMS Study Drug and (ii) any other antibodies that are designed to selectively bind to PD-1 or PD-L1.

"***BMS Indemnitees***" shall have the meaning set forth in Section 11.2.

"***BMS Independent Patent Rights***" means any Patent Rights Controlled by BMS (or its Affiliates) (a) as of the Effective Date or (b) during the Term the subject matter of which was conceived or first reduced to practice through activities other than those performed pursuant to this Agreement, in each case of (a) or (b) that Cover the use (whether alone or in combination with other agents), manufacture, formulation or composition of matter of the BMS Study Drug.

"***BMS Regulatory Documentation***" means any Regulatory Documentation pertaining to the BMS Study Drug that exists as of the Effective Date or that is created during the Term through efforts outside this Agreement.

"***BMS Study Data***" shall have the meaning set forth in Section 8.2.

"***BMS Study Drug***" means BMS's proprietary anti-PD-1 monoclonal antibody product known as Opdivo® (nivolumab).

"***BMS Study Invention***" means any Invention that pertains to (a) the composition of matter of any BMS Class Drug (and not any Recipient Class Drug), (b) method of manufacture or formulation of any BMS Class Drug (and not any Recipient Class Drug) as a Single Agent Compound, and/or (c) a method of use of any BMS Class Drug (and not any Recipient Class Drug) as a monotherapy or as used with other agents, antibodies or compounds (other than an Invention pertaining, whether generically or specifically, to the composition of matter, method of manufacture or formulation, or a method of use of both a BMS Class Drug and a Recipient Class Drug).

"***BMS Study Patent Rights***" means any Patent Rights that Cover any BMS Study Invention (and not a Recipient Study Invention or Combined Therapy Invention), excluding BMS Independent Patent Rights and BMS Technology. For avoidance of doubt, any Patent Rights that cover both (a) a BMS Study Invention and (b) any other type of Invention is included within the Combined Therapy Patent Rights.

"***BMS Technology***" means all Technology Controlled by BMS (or its Affiliates) as of the Effective Date or during the Term created through efforts outside of this Agreement related to the BMS Study Drug or the Combined Therapy and necessary for the conduct of the Combined Therapy Clinical Trial. For clarity, BMS Technology does not include (a) Inventions, (b) Study Data, or (c) Combined Therapy Clinical Trial Regulatory Documentation.

"***Breaching Party***" shall have the meaning set forth in Section 12.2(a).

"***Business Day***" means a day other than Saturday, Sunday or any day on which commercial banks located in New York, NY are authorized or obligated by Applicable Law to close.

"***Clinical Hold***" means that (a) the FDA has issued an order to a Party pursuant to 21 CFR §312.42 to delay a proposed clinical investigation or to suspend an ongoing clinical investigation of the Combined Therapy or such Party's Single Agent Compound in the United States or (b) a Regulatory Authority other than the FDA has issued an equivalent order to that set forth in (a) in any other country or group of countries.

"***Combined Therapy***" means a therapy using the Recipient Study Drug and the BMS Study Drug in combination, with or without another agent.

"***Combined Therapy Clinical Trial***" means the human clinical trial using the Recipient Study Drug and the BMS Study Drug, which will be conducted under the Recipient's protocol (said, protocol, as it may be amended from time to time in accordance with this Agreement, the "***Protocol***") and is incorporated herein by reference. A draft Protocol summary as of the Effective Date is attached as Appendix A hereto. The draft Protocol shall be jointly agreed by the Parties as set forth in Section 2.1(a).

"***Combined Therapy IND***" shall have the meaning set forth in Section 2.1(b).

"***Combined Therapy Invention***" means an Invention that is not a Recipient Study Invention or a BMS Study Invention.

"***Combined Therapy Patent Right(s)***" means any Patent Rights that Cover any Combined Therapy Invention or Combined Therapy Study Data. For clarity, "Combined Therapy Patent Right(s)" do not include any BMS Independent Patent Rights and Recipient Independent Patent Rights.

"***Combined Therapy Clinical Trial Regulatory Documentation***" means any Regulatory Documentation to be submitted for the conduct of the Combined Therapy Clinical Trial, but excluding (a) any Recipient Regulatory Documentation and (b) any BMS Regulatory Documentation.

"***Combined Therapy Study Data***" shall have the meaning set forth in Section 8.2.

"***Commercially Reasonable Efforts***" means, with respect to a Party, the level of effort and resources normally devoted by such Party to conduct a clinical trial for a biopharmaceutical product or compound that is owned by it or to which it has rights, which is of similar market potential, profit potential or strategic value and at a similar stage in its development or product life based on conditions then prevailing.

"***Confidential Information***" shall have the meaning set forth in Section 9.1(a).

"***Control***" or "***Controlled***" means, with respect to particular information or intellectual property, that the applicable Party owns or has a license to such information or intellectual property and has the ability to grant a right, license or sublicense to the other Party as provided for herein without violating the terms of any agreement or other arrangement with any Third Party.

"***Cover***" means, with respect to a Patent Right, that, but for rights granted to a Person under such Patent Right, the practice by such Person of an invention described in such Patent Right would infringe a claim included in such Patent Right, or in the case of a Patent Right that is a patent application, would infringe a claim in such patent application if it were to issue as a patent. "***Covered***" or "***Covering***" shall have correlative meanings.

"***CRO***" means any Third Party contract research organization used to conduct the Combined Therapy Clinical Trial, including laboratories and Third Parties used to maintain the safety database from the Combined Therapy Clinical Trial, but, for clarity, excluding clinical trial sites and any Third Parties who are individuals.

"***Cure Period***" shall have the meaning set forth in Section 12.2(a).

[***]

[***]

"***Date of First Receipt***" means, with respect to a Party, the date on which any employee of such Party, its Affiliates or its Third Party subcontractors first becomes aware of safety-related information.

"***Designated Clinical Contact***" shall have the meaning set forth in Section 2.3.

"***Designated Supply Contact***" shall have the meaning set forth in Section 4.7.

"***Dispute***" shall have the meaning set forth in Section 13.3(b).

"***Effective Date***" shall have the meaning set forth in the preamble to this Agreement.

"***Executive Officers***" means the Chief Executive Officer of the Recipient and the Head of Oncology Development of BMS (or their respective designees).

"***FDA***" means the United States Food and Drug Administration, or any successor agency having the same or similar authority.

"***Filing Party***" shall have the meaning set forth in Section 6.1(c).

"***Global Safety Database***" means the database containing Adverse Events, Serious Adverse Events, Serious Adverse Drug Reactions and pregnancy reports for the Combined Therapy, and shall be the authoritative data source for regulatory reporting and responding to regulatory queries with respect to the Combined Therapy Clinical Trial.

"***Good Clinical Practices***" or "***GCP***" means, as to the United States and the European Union, applicable good clinical practices as in effect in the United States and the European Union, respectively, during the Term and, with respect to any other jurisdiction, clinical practices equivalent to good clinical practices as then in effect in the United States or the European Union.

"***Good Laboratory Practices***" or "***GLP***" means, as to the United States and the European Union, applicable good laboratory practices as in effect in the United States and the European Union, respectively, during the Term and, with respect to any other jurisdiction, laboratory practices equivalent to good laboratory practices as then in effect in the United States or the European Union.

"***Good Manufacturing Practices***" or "***GMP***" means, as to the United States and the European Union, applicable good manufacturing practices as in effect in the United States and the European Union, respectively, during the Term and, with respect to any other jurisdiction, manufacturing practices equivalent to good manufacturing practices as then in effect in the United States or the European Union.

"***ICF***" shall have the meaning set forth in Section 5.1(f).

"***IND***" means (a) an Investigational New Drug Application as defined in the United States Food, Drug and Cosmetic Act, as amended, and regulations promulgated thereunder, or any successor application or procedure required to initiate clinical testing of a drug in humans in the United States, (b) a counterpart of such an Investigational New Drug Application that is required in any other country before beginning clinical testing of a drug in humans in such country, including, for clarity, a "***Clinical Trial Application***" in the European Union, and (c) all supplements and amendments to any of the foregoing.

"***Indemnify***" shall have the meaning set forth in Section 11.1.

"***Infringe***" and "***Infringement***" means any alleged or threatened (in writing) infringement, or misappropriation by a Third Party, of any Patent Rights.

"***Invention***" means any invention or Technology, whether or not patentable, that is made, conceived, or first actually reduced to practice after the Effective Date by, for or on behalf of a Party, or by, for or on behalf of the Parties together (including by a Third Party in the performance of the Combined Therapy Clinical Trial), (a) in relation to the Combined Therapy Clinical Trial to be conducted under this Agreement or (b) by or resulting from the use of Study Data, but excluding in each case any Study Data itself.

"***IRB***" means an Investigational Review Board or Ethics Committee (or similar body in a given country).

"***Licensee***" shall have the meaning set forth in Section 13.10(b).
"***Losses***" shall have the meaning set forth in Section 11.1.

"***Manufacture"*** or "***Manufacturing***" means manufacturing, processing, formulating, packaging, labeling, holding (including storage), and quality control testing of a Single Agent Compound or the Combined Therapy, in each case so as to be suitable for use in the Combined Therapy Clinical Trial under Applicable Law.

"***Material Safety Issue***" means a Party's good faith belief that there is an unacceptable risk for harm in humans based upon: (a) pre-clinical safety data, including data from animal toxicology studies, or (b) the observation of Serious Adverse Events in humans after the Recipient Study Drug or the BMS Study Drug, either as a Single Agent Compound or in combination with another pharmaceutical agent (including as the Combined Therapy), has been administered to or taken by humans, such as during the Combined Therapy Clinical Trial.

"***NDA***" means (a) any new drug application or biologics license application filed with the FDA, or any successor application or procedure required to introduce a drug or biologic into commerce in the United States, (b) a counterpart of such a new drug application or biologics license application that is required in any other country before beginning the commercialization of a drug or a biologic in humans in such country, and (c) all supplements and amendments to any of the foregoing.

"***Non-Breaching Party***" shall have the meaning set forth in Section 12.2(a).

"***Officials***" shall have the meaning set forth in Section 10.9.

"***Ono***" means Ono Pharmaceutical Co., Ltd.

"***Ono-BMS Agreements***" means those certain Collaboration Agreements between BMS and Ono dated as of September 20, 2011 and as of July 23, 2014, as amended from time to time, and agreements between Ono and BMS and their Affiliates relating thereto that may be in effect from time to time.

"***Ono Territory***" means Japan, South Korea and Taiwan.

"***Operational Matters***" shall have the meaning set forth in Section 5.1.

"***Party***" or "***Parties***" shall have the meaning set forth in the preamble to this Agreement.

"***Patent Rights***" means any (a) United States or foreign patents, (b) United States or foreign patent applications, including all provisional applications, substitutions, continuations, continuations-in-part, divisions, renewals, and all patents granted thereon, (c) United States or foreign patents-of-addition, reissues, reexaminations (including *ex parte* reexaminations, *inter partes* reviews, *inter partes* reexaminations, post grant reviews and supplemental examinations) and extensions or restorations by existing or future extension or restoration mechanisms, including supplementary protection certificates, patent term extensions, or the equivalents thereof, and (d) any other form of government-issued right substantially similar to any of the foregoing.

"***Payment***" shall have the meaning set forth in Section 10.9.

"***Person***" means any individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government.

"***Personal Data***" means any information relating to an identified or identifiable natural person.

"***POTV***" shall have the meaning set forth in Section 9.6(a).

"***Protocol***" shall have the meaning set forth in the definition of Combined Therapy Clinical Trial.

"***Publication Dispute***" shall have the meaning set forth in Section 9.5(b).

"***Quarter***" means a calendar quarter.

"***Recipient Class Drug***" means the Recipient Study Drug and any oncolytic virus derived from a potent herpes simplex virus strain expressing gibbon ape leukemia virus glycoprotein and eliciting anti-tumor activity.

"***Recipient Indemnitees***" shall have the meaning set forth in Section 11.1.

"***Recipient Independent Patent Rights***" means any Patent Rights Controlled by the Recipient or a Recipient Affiliate (a) as of the Effective Date or (b) during the Term the subject matter of which was conceived or first reduced to practice through activities other than those performed pursuant to this Agreement, in each case (a) and (b) that Cover the use (either alone or in combination with other agents), manufacture, formulation or composition of matter of the Recipient Study Drug.

"***Recipient Regulatory Documentation***" means any Regulatory Documentation pertaining to the Recipient Study Drug that exists as of the Effective Date or that is created during the Term through efforts outside this Agreement.

"***Recipient Study Data***" shall have the meaning set forth in Section 8.2.

"***Recipient Study Drug***" means the Recipient's proprietary oncolytic virus known as RP-2.

"***Recipient Study Invention***" means any Invention that pertains to (a) the composition of matter of any Recipient Class Drug (and not any BMS Class Drug), (b) method of manufacture or formulation of any Recipient Class Drug (and not any BMS Class Drug) as a Single Agent Compound, or (c) a method of use of the Recipient Class Drug (and not any BMS Class Drug) as a monotherapy or as used in combination with other agents, antibodies or compounds (other than Invention pertaining, whether generically or specifically, to the composition of matter, method of manufacture, formulation or a method of use of both a BMS Class Drug and a Recipient Class Drug.

"***Recipient Study Patent Rights***" means any Patent Rights that Cover any Recipient Study Invention (and not a BMS Study Invention or a Combined Therapy Invention), excluding Recipient Independent Patent Rights and Recipient Technology. For avoidance of doubt, any Patent Rights that cover both (a) a Recipient Study Invention and (b) any other type of Invention is included within the Combined Therapy Patent Rights.

"***Recipient Technology***" means all Technology Controlled by the Recipient or a Recipient Affiliate as of the Effective Date or during the Term which is created through efforts outside of this Agreement related to the Recipient Study Drug or the Combined Therapy and necessary for the conduct of the Combined Therapy Clinical Trial. For clarity, Recipient Technology does not include (a) Inventions, (b) Study Data, or (c) Combined Therapy Clinical Trial Regulatory Documentation.

"***Regulatory Authority***" means the FDA or any other governmental authority outside the United States (whether supranational, national, federal, provincial and/or local) that is the counterpart to the FDA, including the European Medicines Agency for the European Union.

"***Regulatory Documentation***" means, with respect to a Party's Single Agent Compound, all submissions to Regulatory Authorities in connection with the development of such Single Agent Compound, as applicable, including all INDs and amendments thereto, NDAs and amendments thereto, drug master files, correspondence with regulatory agencies, periodic safety update reports, adverse event files, complaint files, inspection reports and manufacturing records, in each case together with all supporting documents (including documents that include clinical data).

"***Results***" shall have the meaning set forth in Section 9.5(b).

"***Right of Cross-Reference***" means, with regard to a Party, allowing the applicable Regulatory Authority in a country to have access to relevant information (by cross-reference, incorporation by reference or otherwise) contained in Regulatory Documentation (and any data contained therein) filed with such Regulatory Authority with respect to a Party's Single Agent Compound (and, in the case of BMS, the Right to Cross-Reference the Combined Therapy IND), only to the extent necessary for the conduct of the Combined Therapy Clinical Trial in such country or as otherwise expressly permitted or required under this Agreement to enable a Party to exercise its rights or perform its obligations hereunder, and, except as to information contained in the Combined Therapy IND pertaining to the Combined Therapy, without the disclosure of such information to such Party.

"***RP-1 Agreement***" shall have the meaning set forth in the Preliminary Statements.

"***Safety Issue***" means any information suggesting an emerging safety concern or possible change in the risk-benefit balance for a drug, including information on a possible causal relationship between an Adverse Event and a drug, the relationship being unknown or incompletely documented previously.

"***Safety Signal***" means information arising from one or multiple sources, including observations and experiments, which suggests a new potentially causal association, or a new aspect of a known association between an intervention and an event or set of related events, either adverse or beneficial, that is judged to be of sufficient likelihood to justify verificatory action.

"***Samples***" means biological specimens collected from Combined Therapy Clinical Trial study subjects (including fresh and/or archived tumor samples, serum, peripheral blood mononuclear cells, plasma, and whole blood for RNA and DNA sample isolation).

"***Shortage***" shall have meaning set forth in Section 4.5.

"***Single Agent Compound***" or "***Compound***" means, with respect to (a) the Recipient, the Recipient Study Drug, as monotherapy, and (b) BMS, the BMS Study Drug, as monotherapy.

"***Sponsor***" means an applicant or holder of clinical studies applications/notifications.

"***Study Data***" shall have the meaning set forth in Section 8.1.

"***Sunshine Laws***" shall have the meaning set forth in Section 9.6(c).

"***Supply and Quality Documentation***" shall have the meaning set forth in Section 4.3.

"***Technology***" means information, inventions, discoveries, trade secrets, knowledge, technology, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, specifications, data and results not generally known to the public (including biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and know-how, including study designs and protocols), in all cases, whether or not patentable, in written, electronic or any other form now known or hereafter developed and materials, including Regulatory Documentation.

"***Term***" shall have the meaning set forth in Section 12.1.

"***Territory***" means the United States, including Puerto Rico, and the European Union (including the United Kingdom, whether or not an EU member state). For clarity, the Territory excludes the Ono Territory.

"***Third Party***" means any Person or entity other than the Recipient and BMS and their respective Affiliates.

"***Third Party Claim***" shall have the meaning set forth in Section 11.1.

"***Third Party License Payments***" means any payments (e.g., upfront payments, milestones, royalties) due to any Third Party under license agreements or other written agreements granting rights to intellectual property owned or controlled by such Third Party to the extent that such rights are necessary for (a) the making, using or importing of a Party's Single Agent Compound for the conduct of the Combined Therapy Clinical Trial, or (b) the conduct of the Combined Therapy Clinical Trial.

"***TP Study Costs***" shall have the meaning set forth in Section 7.2.

ARTICLE 2
SCOPE

2.1 Scope.

(a) The Recipient will conduct the Combined Therapy Clinical Trial in accordance with the Protocol and the terms of this Agreement. The Parties will use good faith efforts to jointly agree on a draft Protocol within [***] following the Effective Date, which shall be based on the draft Protocol summary attached as Appendix A hereto. The Recipient shall be solely responsible for the content of the Protocol following agreement by the Parties on the draft Protocol; *provided that*: (i) the Recipient will notify BMS of any proposed amendments to the draft Protocol agreed by the Parties (or to the final Protocol initially approved by an IRB) and the Recipient will consider any comments provided by BMS regarding the proposed amendments (it being understood that the Parties will endeavor to set forth in writing the circumstances (e.g., administrative matters) where it may be feasible for the Recipient to make specific Protocol amendments without the need for BMS to comment), and (ii) any changes to the draft Protocol agreed by the Parties (or to the final Protocol initially approved by an IRB) that pertain to the administration of the BMS Study Drug must be reviewed and expressly approved by BMS in writing or the change may not be implemented. BMS shall have [***] from the date on which the Recipient provides the applicable Protocol amendment to BMS to approve or provide any comments to the Recipient concerning the proposed amendment. For clarity, Recipient shall not conduct any patient recruitment activities for, or otherwise initiate, the Combined Therapy Clinical Trial until the draft Protocol is jointly agreed by the Parties.

(b) The Combined Therapy Clinical Trial shall be conducted under a combination IND, for which the Recipient will be the sponsor of record (the "***Combined Therapy IND***") and shall be conducted only in the Territory. The Recipient shall be the sole holder of all legal interests in the Combined Therapy IND; *provided, however, that* the Recipient may not grant any Third Party any Right of Cross-Reference with respect to any portion of the Combined Therapy IND pertaining to BMS's Single Agent Compound for use as monotherapy or for use in combination with any molecules, agents, antibodies or compounds other than the Recipient Study Drug.

(c) BMS will make available its current package insert for the BMS Study Drug in the Territory available to the Recipient and will provide any updates thereto at the same time as the same are made publicly available.

(d) If the Recipient and BMS agree that the Recipient will require access to the investigator's brochure for the BMS Study Drug in order for the site to conduct the Combined Therapy Clinical Trial, then (i) BMS will provide the current version of its investigator brochure to the Recipient promptly and (ii) will thereafter, until the conclusion of the Combined Therapy Clinical Trial, provide to the Recipient, upon reasonable request, the latest investigator's brochure for the BMS Study Drug or any amendments thereto in accordance with BMS's customary practices for same. The Recipient shall, and shall require that any clinical trial sites for the Combined Therapy Clinical Trial shall, use any such data provided pursuant to this Section 2.1(d) solely (A) to evaluate the safety and efficacy of the BMS Study Drug and the Combined Therapy for use in Combined Therapy Clinical Trial, (B) to meet any regulatory requirements pertaining to the conduct of the Combined Therapy Clinical Trial and (C) to enable the Recipient to draft and update as necessary the investigator's brochure for the Combined Therapy Clinical Trial. The Recipient will ensure that clinical trial sites for the Combined Therapy Clinical Trial are obligated to protect such

information and disclosures as set forth in Article 9. The Recipient's right to use the investigator's brochure provided by BMS shall terminate upon the completion or termination of the Combined Therapy Clinical Trial and shall not be used for purposes of conducting any other clinical studies.

(e) If requested in writing by the Recipient and agreed to by BMS (such consent not to be unreasonably withheld), BMS shall provide a Right of Cross-Reference as needed to its existing Regulatory Documentation for BMS's Single Agent Compound for those countries in the Territory where the Combined Therapy Clinical Trial will be conducted solely as necessary to allow the Combined Therapy Clinical Trial to be conducted under the Combined Therapy IND in an applicable country; *provided that* such Right of Cross-Reference shall terminate upon the expiration or termination of this Agreement and shall not be used for purposes of conducting any other clinical studies, except that, in the case of termination for a Material Safety Issue pursuant to Section 12.4, such Right of Cross-Reference shall remain in effect solely (i) to the extent necessary to permit the Recipient to comply with any outstanding obligations required by a Regulatory Authority and/or Applicable Law or (ii) as necessary to permit the Recipient to continue to dose subjects enrolled in the Combined Therapy Clinical Trial through completion of the Protocol if required by the applicable Regulatory Authority(ies) and/or Applicable Laws.

(f) If PDL-1 biomarker testing is incorporated into the Protocol, the Recipient agrees to use the commercially available [*******] to perform such testing.

(g) The Recipient shall refer to the applicable BMS Study identification number in all Combined Therapy Clinical Trial reports, reports of Serious Adverse Events, BMS Study Drug requests, and all other material submissions or communications to BMS relating to the Protocol.

2.2 Adverse Event Reporting.

(a) This Section 2.2 shall govern safety reporting arising from the Combined Therapy Clinical Trial. The Recipient will manage all drug safety reporting activities for the Combined Therapy Clinical Trial.

(b) The Recipient will forward to BMS at the contact information below via fax or secure e-mail in a format to be agreed to by the Parties all fatal or life threatening SAE reports within four (4) calendar days of Date of First Receipt, all other SAE reports, reports of exposure during pregnancy (maternal and paternal) and reports of suspected transmission of an infectious agent via the BMS Study Drug or Combined Therapy within nine (9) calendars days of Date of First Receipt, in each case for the BMS Study Drug and the Combined Therapy administered in the Combined Therapy Clinical Trial.

BMS — Adverse Event Reporting Contact	
E-mail	[*******]
Fax	[*******]
Acknowledgment of ICSR receipt:	[*******]

(c) Each Party shall collect, use and disclose Personal Data obtained in the course of performing the pharmacovigilance activities under this Section 2.2 solely for the purposes of complying with the regulatory obligations as described in this Agreement, or as otherwise required by Applicable Law or by a court order. Both Parties will use electronic, physical, and other safeguards appropriate to the nature of the information to prevent any use or disclosure of Personal Data other than as provided for by this Agreement and permitted under the ICF. Both Parties will also take reasonable precautions to protect such Personal Data from accidental, unauthorized, or unlawful alteration or destruction. Each Party will notify the other Party promptly of any accidental, unauthorized, or unlawful destruction, loss, alteration, or disclosure of, or access of such Personal Data.

(d) The Recipient will promptly make available to BMS upon request such records that the Recipient Controls as is necessary or useful to perform medical assessment of any Adverse Event associated with the use of the BMS Study Drug or Combined Therapy reported during the Combined Therapy Clinical Trial that is forwarded to BMS under this Agreement. The Recipient will designate a single point of contact within its organization (and will provide to BMS the email address of such point of contact prior to the start of the Combined Therapy Clinical Trial) for any pharmacovigilance-related follow-up questions that BMS would have.

(e) The Recipient shall perform case level reconciliation to confirm that BMS has received all reports required under this Agreement. The Recipient shall e-mail [*******] to request a reconciliation report for the Combined Therapy Clinical Trial. The Recipient shall reconcile the cases identified as being transmitted to BMS on BMS's reconciliation report and those contained in the Combined Therapy Clinical Trial database. The Recipient shall send missing case-level events to BMS Global Pharmacovigilance at [*******] or by fax at [*******]. The Recipient shall perform such reconciliation every [*******], unless otherwise agreed by BMS in writing.

(f) As Sponsor, the Recipient will be responsible for submitting all applicable Individual Case Safety Report (ICSRs) and aggregate report submissions to Regulatory Authorities for the Combined Therapy Clinical Trial. The Recipient will provide BMS with the final version of any aggregate report at the time of submission. The Recipient will also submit appropriate safety letters or safety reports to study investigators, the reviewing IRB and authorized Regulatory Authorities in accordance with Applicable Law.

(g) In the event that BMS produces any Development Safety Update Report ("***DSUR***") in respect to the BMS Study Drug, BMS will provide to the Recipient upon request, and for the duration of the Combined Therapy Clinical Trial, copies of the executive summary and any line listings of Serious Adverse Drug Reactions extracted from the final DSUR for information purposes only and to assist the Recipient in generation of their own clinical trial aggregate report, where applicable. The Recipient agrees not to forward such BMS DSUR sections to any Third Party, except to its Affiliates, consultants, advisors and contractors under obligations of confidentiality for generation of such a clinical trial aggregate report or as otherwise permitted with respect to BMS Confidential Information under Section 9.3(b), (d), (e), and (f).

(h) If the Recipient determines there is a significant Safety Issue or significant Safety Signals arising in a clinical trial that may be associated with the BMS Study Drug or Combined Therapy, the Recipient will disclose such information to BMS promptly after such determination.

(i) BMS will ensure that any urgent Safety Issues or Safety Signals relating to the BMS Study Drug will be communicated to the Recipient promptly after such determination.

2.3 Clinical Study Designated Contact. Each Party will designate an employee within its organization (the "***Designated Clinical Contact***") who will coordinate and/or facilitate:

(a) the review of Protocol amendments submitted by the Recipient for BMS approval and with whom comments thereon may be discussed;

(b) any BMS clinical and regulatory responsibilities and communications regarding the Combined Therapy Clinical Trial;

(c) internal BMS review of any document or regulatory communication and the provision of any BMS comments; and

(d) discussion of any other topics or issues relating to the Combined Therapy Clinical Trial requested by the Recipient or BMS.

2.4 Conduct. Each Party shall use Commercially Reasonable Efforts to (a) perform and fulfill its respective activities under the Combined Therapy Clinical Trial and this Agreement on a timely basis and in an effective manner consistent with prevailing standards, (b) supply the quantities of its Compound in accordance with Article 4 as needed to conduct the Combined Therapy Clinical Trial on a timely basis, and, in the case of the Recipient, package and deliver same to study sites on a timely basis, and (c) in the case of the Recipient, conduct and complete the Combined Therapy Clinical Trial on a timely basis in accordance with the Protocol and Third Party agreements relating thereto, and provide sufficient resources, funding and personnel to conduct and perform the Combined Therapy Clinical Trial on a timely basis in accordance with the Protocol for same and the terms of this Agreement. Each Party shall perform its duties for the Combined Therapy Clinical Trial in accordance with Applicable Law, including GCP, GLP and GMP as applicable.

ARTICLE 3

LICENSE GRANTS

3.1 Grant by BMS. Subject to the terms of this Agreement, BMS hereby grants, and shall cause its Affiliates to grant, to the Recipient a non-exclusive, non-transferable, royalty-free license (with the right to sublicense solely pursuant to the terms of and subject to the limitations of Section 3.2) under the BMS Independent Patent Rights and BMS Technology to use the BMS Study Drug solely within the Territory and solely to the extent necessary to discharge the Recipient's obligations under this Agreement with respect to the conduct of the Combined Therapy Clinical Trial in the Territory.

3.2 Sublicensing.

(a) The Recipient shall have the right to grant sublicenses under the licenses granted to it under Section 3.1, to Affiliates and to Third Parties, if required for an Affiliate or a Third Party to perform its duties with respect to the conduct of the Combined Therapy Clinical Trial, solely as necessary to assist the Recipient in carrying out its responsibilities with respect to the Combined Therapy Clinical Trial.

(b) With regard to any such sublicenses permitted and made under this Agreement, (i) the sublicensees, except Affiliates (so long as they remain Affiliates of a Party), shall be subject to written agreements that bind such sublicensees to obligations that are consistent with a Party's obligations under this Agreement including confidentiality and non-use provisions no less restrictive than those set forth in herein, and provisions regarding intellectual property that ensure that the Parties will have the rights provided under this Agreement to any intellectual property relating to their Single Agent Compound and/or the Combined Therapy created by such sublicensee, (ii) each Party shall provide written notice to the other Party of any such sublicense (and obtain approval for sublicenses to Third Parties other than clinical trial sites); and (c) the licensing Party shall remain liable to the other Party for all actions of the sublicensing Party's sublicensees.

3.3 No Implied Licenses. Unless and except as specifically set forth in this Agreement, neither Party shall acquire any license or other intellectual property interest, by implication or otherwise, in any intellectual property of the other Party, including Confidential Information disclosed to it under this Agreement or under any Patent Rights Controlled by the other Party or its Affiliates.

ARTICLE 4

MANUFACTURE AND SUPPLY

4.1 Recipient Study Drug Manufacture and Supply.

(a) The Recipient shall be responsible, at its sole costs and expense, for manufacturing, packaging and labeling (or having manufactured, packaged or labeled) GMP-grade quantities of the Recipient Study Drug, as well as obtaining any other drug (other than the BMS Study Drug provided by BMS pursuant to Section 4.2) required for the conduct of the Combined Therapy Clinical Trial, and shall package and label if and as required by the Protocol and/or applicable Regulatory Authorities all drugs (including the BMS Study Drug) used in the Combined Therapy Clinical Trial, on a timely basis and in accordance with applicable specifications as required for the conduct of the Combined Therapy Clinical Trial. The Recipient Study Drug shall be manufactured in accordance with Applicable Law (including GMP) and shall be of similar quality to the Recipient Study Drug used by the Recipient for its other clinical trials of the Recipient Study Drug.

(b) The Recipient shall provide BMS with prompt notice of any Manufacturing and supply issues with respect to the Recipient Study Drug, or any defects or manufacturing problems identified with respect to the BMS Study Drug supplied to Recipient, that may adversely impact the conduct or timelines of the Combined Therapy Clinical Trial.

4.2 BMS Study Drug.

(a) Manufacture and Supply. BMS shall Manufacture or have Manufactured the BMS Study Drug in reasonable quantities needed, and at the points in time as agreed to by the Parties, for the Combined Therapy Clinical Trial, and shall supply such BMS Study Drug as either commercially labeled or unlabeled vials to the Recipient or its designee for use solely in the Combined Therapy Clinical Trial. The Recipient will at its sole expense, package and label the BMS Study Drug for use in the Combined Therapy Clinical Trial to the extent necessary. The cost of Manufacture and supply (including shipping, taxes and duty, if applicable) of the BMS Study Drug for the Combined Therapy Clinical Trial shall be borne solely by BMS, and BMS shall bear the risk of loss for such quantities of BMS Study Drug until delivery of such quantities of BMS Study Drug to the Recipient or its designee. BMS shall also be responsible for the payment of any Third Party License Payments that may be due based on the manufacture, supply and use of the BMS Study Drug used in the Combined Therapy Clinical Trial. The BMS Study Drug shall be manufactured in accordance with Applicable Law (including GMP) and shall be of similar quality to the BMS Study Drug used by BMS for its other clinical trials of the BMS Study Drug. BMS shall deliver certificates of analysis, and any other documents specified in the Supply and Quality Documentation, including such documentation as is necessary to allow the Recipient to compare the BMS Study Drug certificate of analysis to the BMS Study Drug specifications. Pursuant to the Supply and Quality Documentation, BMS shall be responsible for the regulatory compliance of the quality of the BMS Study Drug at the time the BMS Study Drug is delivered to the Recipient with the regulatory filings in the countries in the Territory where the Combined Therapy Clinical Trial will be performed. Subject to Section 4.4, the Parties shall cooperate in accordance with Applicable Law to minimize indirect taxes (such as value added tax, sales tax, consumption tax and other similar taxes) relating to the BMS Study Drug in connection with this Agreement.

(b) Use of BMS Study Drug Supplied by BMS to the Recipient. The Recipient shall use the quantities of BMS Study Drug supplied to it under this Agreement solely as necessary for, and in accordance with, this Agreement and the Protocol, and for no other purpose, including as a reagent or tool to facilitate its internal research efforts, for any commercial purpose, or for other clinical or non-clinical research unrelated to the Combined Therapy Clinical Trial. Except as may be required or expressly permitted by the Protocol or the Supply and Quality Documentation, the Recipient shall not perform, and shall not allow any Third Party to perform, any analytical testing of the quantities of BMS Study Drug supplied to it under this Agreement. If Study Drug supplied by BMS is lost, damaged, destroyed or becomes unable to comply with applicable specifications while under the control of the Recipient or any of its (sub)contractors, including common carriers and clinical study sites contracted by the Recipient, BMS shall not be obligated to replace same, and if BMS does elect to do so, BMS may elect to charge the Recipient a reasonable replacement cost to replace same. Notwithstanding Section 4.2(b) of the RP-1 Agreement, the Recipient may use BMS Study Drug supplied to it under the RP-1 Agreement (to the

extent such BMS Study Drug is not necessary for the purposes of the RP-1 Agreement) pursuant to this Section 4.2(b) as though it was supplied under this Agreement.

4.3 Supply and Quality Documentation. BMS shall supply the BMS Study Drug to the Recipient in accordance with such supply and quality addenda or agreement(s) as the Parties may agree (the "***Supply and Quality Documentation***"). The Parties shall finalize and execute the Supply and Quality Documentation within [*******] of the Effective Date, but in no event later than the date on which the first shipment of the BMS Study Drug is supplied for use in the Combined Therapy Clinical Trial. The Supply and Quality Documentation shall outline the additional roles and responsibilities relative to the quality of BMS Study Drug in support of the Combined Therapy Clinical Trial. It shall include the responsibility for quality elements as well as exchanged GMP documents and certifications required to release the BMS Study Drug for the Combined Therapy Clinical Trial. In addition, the Supply and Quality Documentation shall detail the documentation required for each shipment of BMS Study Drug supplied to the Recipient or its designee for use in the Combined Therapy Clinical Trial.

4.4 Supply Forecast. Estimated supply and delivery details will be outlined in the Supply and Quality Documentation and will be updated by the Parties by mutual agreement (which agreement can be effected by the Parties' Designated Supply contacts and without need for an amendment to this Agreement) based on the actual enrollment. The Recipient will promptly inform BMS of any change in its requirements, and BMS will endeavor to accommodate any change in the supply quantities requested by the Recipient so long as it does not unduly disrupt BMS's ongoing business activities.

4.5 Shortages. BMS shall provide the Recipient with prompt notice of any Manufacturing and supply issues with respect to the BMS Study Drug that may adversely impact the conduct or timelines of the Combined Therapy Clinical Trial. In the event of a supply interruption or shortage of BMS Study Drug as determined by BMS pursuant to its internal processes and policies (a "***Shortage***"), such that BMS reasonably believes that it will not be able to fulfill its supply obligations under this Agreement, BMS will provide prompt written notice thereof to the Recipient (including the quantity of BMS Study Drug that BMS reasonably estimates it will be able to supply) and, upon request, the Parties will promptly discuss such situation (including how the quantities of BMS Study Drug that BMS is able to supply under this Agreement will be allocated within the Combined Therapy Clinical Trial). Notwithstanding anything to the contrary contained herein, in the event of a Shortage of the BMS Study Drug, BMS will have sole discretion, subject to Applicable Law, to determine the quantity of BMS Study Drug it will be able to supply as a result of such Shortage; provided, however, that BMS shall consider in good faith the needs of patients who are actively being treated with BMS Study Drug, including Combined Therapy Clinical Trial patients, in making such determination. BMS will not be deemed to be in breach of this Agreement for failure to supply any other quantities of BMS Study Drug hereunder as a result of a Shortage. Any such allocation of the BMS Study Drug in accordance with this Section 4.5 will be the Recipient's exclusive remedy with respect to a Shortage.

4.6 Customs Valuation. The Recipient will provide BMS in writing with a list of each country in which it proposes to conduct the Combined Therapy Clinical Trial prior to execution of any site agreement or CRO agreement for that country. During the conduct of the Combined Therapy Clinical Trial, the Recipient will send in writing any changes to the list of participating countries to BMS one month prior to the end of each Quarter. If no changes are sent to BMS by the Recipient for a particular Quarter, the prior Quarter's participating country list will be used as the basis for customs valuation for that Quarter. BMS will provide the Recipient with country-specific customs valuations initially for the BMS Study Drug prior to initiation of the Combined Therapy Clinical Trial and at the end of each Quarter during the conduct of the Combined Therapy Clinical Trial. The Recipient will use the BMS provided values for the import/export process to the listed participating countries and not make any change to such valuations without BMS's prior written consent.

4.7 Designated Supply Contact. Each Party will designate an individual (the "***Designated Supply Contact***") that a Party may contact to assist with coordinating supplies and facilitating the resolution of any issues or concerns arising in connection with the supply of the BMS Study Drug for use in the Combined Therapy Clinical Trial.

ARTICLE 5

RESPONSIBILITIES

5.1 Specific Responsibilities of the Recipient. The Recipient shall, subject to the terms of the Protocol, applicable terms and conditions of this Agreement, and any other agreement between the Parties relating to the Combined Therapy Clinical Trial, manage and be responsible for the conduct of the Combined Therapy Clinical Trial, including timelines and contingency planning. In particular, and not in limitation of the foregoing, the Recipient shall perform (itself and/or through Third Parties, including clinical trial sites, CROs and investigators) and/or be responsible for the following (items (a) to (p) below, collectively the "***Operational Matters***") with respect to the Combined Therapy Clinical Trial:

(a) compiling, amending and filing all necessary Combined Therapy Clinical Trial Regulatory Documentation with Regulatory Authority(ies), maintaining and acting as the sponsor of record as provided in 21 CFR 312.50 (and applicable comparable ex-US laws) with responsibility, unless otherwise delegated in accordance with 21 CFR 312.52 (and applicable comparable ex-US laws), for the Combined Therapy Clinical Trial and making all required submissions to Regulatory Authorities related thereto on a timely basis;

(b) conducting clinical study start-up activities, communicating with and obtaining approval from IRBs for the Protocol and other relevant documents for the Combined Therapy Clinical Trial as applicable, as well as patient recruitment and retention activities;

(c) listing of the Combined Therapy Clinical Trial, if it is required to be listed on a public database on www.clinicaltrials.gov or other public registry in any country in which such Combined Therapy Clinical Trial is being conducted, all in accordance with Applicable Law and in accordance with its internal policies relating to clinical trial registration;

(d) providing BMS with reasonable advance notice of scheduled meetings or other pre-planned non-written communications with a Regulatory Authority and the opportunity to participate in each such meeting or other non-written communication, to the extent involving a safety, efficacy or toxicology issue relating to the Combined Therapy or the BMS Study Drug or any other matter related to the Combined Therapy or Combined Therapy Clinical Trial that it determines in its reasonable judgement could potentially have an adverse effect on the BMS Study Drug. In such case, the Recipient will provide BMS with the opportunity to review, provide comments to the Recipient within [***] on, and, if inconsistent with the Protocol, approve all submissions and written correspondence with a Regulatory Authority that relates to the BMS Study Drug;

(e) provide BMS (i) a written notice to the BMS Designated Clinical Contact (via email to the email address designated by BMS) of meetings or other substantive non-written communications with a Regulatory Authority within [***] of such meeting or communication, and if requested by BMS following such notice, a written summary of such meeting or communication within ten (10) days of such request, and (ii) copies of any official correspondence to or from a Regulatory Authority within [***] of receipt or provision, in each case of (i) or (ii) to the extent involving a safety, efficacy or toxicology issue relating to the Combined Therapy or the BMS Study Drug or any other matter related to the Combined Therapy or Combined Therapy Clinical Trial that it determines in its reasonable judgement could potentially have an adverse effect on the BMS Study Drug, and copies of all material Combined Therapy Clinical Trial Regulatory Documentation and correspondence that relates to same within [***] of submission to Regulatory Authorities;

(f) subject to the terms of this Agreement, the selection and payment of, negotiation of the terms of, contracting with, managing and overseeing compliance of its agreement by and the receipt of contract deliverables from, any CRO or vendor selected by the Recipient to assist in the performance of the Combined Therapy Clinical Trial. The Recipient shall determine and approve contract deliverables and manage contract performance, including executing site contracts, drafting and obtaining IRB approval for site informed consent forms (each an "***ICF***"), obtaining signed ICFs, monitoring plans, etc. The Recipient will be responsible for ensuring that all such contracts and ICFs: (i) do not conflict with the terms of this Agreement, (ii) allow the Recipient to provide BMS with access to and use of Study Data, Samples, and

other information and documents as required pursuant to this Agreement (and in no event less than the same use rights granted to the Recipient), (iii) do not impose a new obligation, whether direct, indirect, or contingent, upon BMS that is not set forth in this Agreement, and (iv) retain each of the Parties' respective intellectual property rights in and access to the BMS Technology, BMS Independent Patent Rights, Study Data, Samples, Recipient Study Drug, BMS Study Drug and Combined Therapy consistent with this Agreement, and (vi) comply with Applicable Law;

(g) providing BMS (if requested by BMS) with copies of each final site template of the Combined Therapy Clinical Trial's ICF. The Recipient shall ensure that each ICF does not impose any financial obligation, liability, damages or other cost upon BMS with respect to any injury (including death) suffered by a Combined Therapy Clinical Trial subject whether or not resulting from the administration of the BMS Study Drug or direct a study subject to BMS to seek reimbursement for any costs or seek compensation for any injury incurred in connection with the Combined Therapy Clinical Trial;

(h) if requested by BMS, providing BMS within [***] with minutes from any and all external drug safety monitoring boards for the Combined Therapy Clinical Trial after receipt by the Recipient, to the extent relating to the BMS Study Drug or the Combined Therapy;

(i) informing and updating BMS on a [***] basis (with significant issues to be communicated promptly after the Recipient becomes aware of same) regarding all Operational Matters, so that if BMS has any significant concerns or material disagreements regarding same, the matter can be discussed with the Recipient. Without limiting the foregoing, the Recipient shall inform BMS [***] as to the overall Combined Therapy Clinical Trial progress, [***], and any other Combined Therapy Clinical Trial-related matters requested by BMS to the extent involving a safety, efficacy or toxicology issue relating to the Combined Therapy or the BMS Study Drug or any other matter that could have an adverse effect on the BMS Study Drug;

(j) owning and being responsible for (or appointing a Third Party to be responsible for) the maintenance of the Global Safety Database and being responsible for safety reporting, collecting, evaluating and reporting Serious Adverse Events, other safety data and any further pharmacovigilance information from the Combined Therapy Clinical Trial;

(k) analyzing the Study Data in a timely fashion and providing BMS with access to the Study Data as follows:

(i) top line data and a copy of all Clinical Study Reports (CSRs), in each case, as and when received by the Recipient's clinical management;

(ii) if requested by BMS, sharing with BMS for review and comment drafts of interim and/or final clinical trial report (and/or statistical analysis in accordance with the Protocol) from the Combined Therapy Clinical Trial;

(iii) if requested by BMS, within [***] after database lock, access to those safety databases that will be used for any interim review by an external consultant (or drug safety monitoring board, if required);

(iv) if requested by BMS, within [***] after database lock, access to case report forms or patient profiles for all patients in the Combined Therapy Clinical Trial;

(v) if requested by BMS, within [***] of the creation of an electronic clean database for the Combined Therapy Clinical Trial, an electronic copy of the clean database (the form and format of the clean database to be reasonably acceptable to both Parties);

(vi) if requested by BMS, subject to any third party requirements, providing BMS with any programs or SAS codes to be used for any statistical analysis plan for the Combined Therapy Clinical Trial; and

(vii) (A) safety analyses, (B) new and/or changing Safety Signals and Safety Issues, (C) new and/or changing toxicology and efficacy signals, and (D) any statistical analysis, immunogenicity analysis, or bioanalysis, in each case relating to the BMS Study Drug, the Recipient Study Drug and/or the Combined Therapy, as and when the same are received by the Recipient;

(l) obtaining supplies of any co-medications, to the extent any such co-medications are required for use in the Combined Therapy Clinical Trial, and providing to BMS any information related to the Combined Therapy Clinical Trial that is provided to the manufacturer of any co-medication within [***] after the provision of the information to the manufacturer;

(m) if requested by BMS, information that Recipient has available to it as of such time (and with no duty to conduct any interim analysis) regarding either (i) the pharmacokinetics and safety of the Recipient Study Drug alone or (ii) the pharmacokinetics, efficacy and safety of the Recipient Study Drug in combination with the BMS Study Drug;

(n) performing either directly or through third parties collection of Samples required by the Protocol;

(o) handling and addressing inquiries from the Combined Therapy Clinical Trial subjects and investigators; and

(p) such other responsibilities as may be agreed to by the Parties.

5.2 BMS Operational Responsibilities. BMS shall be responsible for the following activities:

(a) Manufacturing and supplying GMP-grade quantities of the BMS Study Drug, as further described in Article 4 above, and, where and to the extent provided in the Supply and Quality Documentation, providing necessary GMP information and documentation that enables the Recipient Qualified Person (as such term will be defined in the Supply and Quality Documentation) to release BMS Study Drug for the Combined Therapy Clinical Trial;

(b) where and to the extent provided in the Supply and Quality Documentation, providing for the release by a Qualified Person or providing the necessary documentation in support of such quality release, of the BMS Study Drug if such release is required for the Combined Therapy Clinical Trial;

(c) to the extent necessary for the conduct of the Combined Therapy Clinical Trial, providing a Right of Cross-Reference to the relevant Regulatory Documentation for the BMS Study Drug as set forth in Section 2.1(b) and/or (e), if applicable, to the BMS investigator's brochure for the BMS Study Drug (and updates thereto) as provided in Section 2.1(d); and

(d) such other responsibilities as may be agreed to by the Parties.

5.3 Other Clinical Trials. Nothing in this Agreement shall preclude either Party from conducting any other clinical trials as it may determine in its discretion, so long as it does not use or rely on the Confidential Information that is solely owned by the other Party in doing so.

5.4 Potential Subsequent Studies. During the Term, each of the Parties agrees to discuss in good faith, for a period of no longer than [***], additional Combined Therapy Clinical Trials of the BMS Study Drug with the Recipient Study Drug (and/or follow-on versions of the Recipient Study Drug). If the Parties jointly agree to conduct any such further clinical trials (each, a "***Subsequent Study***"), this Agreement and the Supply and Quality Documentation shall be amended to provide for such Subsequent Study under the terms thereof. The Parties agree to discuss whether it may be useful or desirable to include Ono as part of a Subsequent Study. For clarity, no Party shall be obligated to collaborate with the other Party or agree on terms with the other Party with respect to any additional clinical trials (or other collaboration opportunities) pursuant to this Section 5.4.

ARTICLE 6

INTELLECTUAL PROPERTY

6.1 Inventions and Related Patent Rights. All rights to Inventions shall be allocated as follows:

(a) Recipient Ownership. Subject to the terms of this Agreement, all Recipient Study Inventions and Recipient Study Patent Rights shall be owned solely by the Recipient, and the Recipient will have the full right to exploit such Recipient Study Inventions and Recipient Study Patent Rights without the consent of, or any obligation to account to, BMS. BMS shall assign and hereby assigns (and shall cause its Affiliates and contractors to assign) its right, title and interest in any Recipient Study Inventions and Recipient Study Patent Rights to the Recipient. BMS shall execute such further documents and provide other assistance as may be reasonably requested by the Recipient to perfect the Recipient's rights in such Recipient Study Inventions and Recipient Study Patent Rights, all at the Recipient's expense. The Recipient shall have the sole right but not the obligation to prepare, file, prosecute (including any proceedings relating to reissues, reexaminations, protests, interferences, oppositions, post-grant reviews or similar proceedings and requests for patent extensions) and maintain any Recipient Study Patent Rights at its own expense.

(b) BMS Ownership. Subject to the terms of this Agreement, all BMS Study Inventions shall be owned solely by BMS, and BMS will have the full right to exploit such BMS Study Inventions without the consent of, or any obligation to account to, the Recipient. The Recipient shall assign and hereby assigns (and shall cause its Affiliates and contractors to assign) all its right, title and interest in any BMS Study Inventions and BMS Study Patent Rights to BMS. The Recipient shall execute such further documents and provide other assistance as may be reasonably requested by BMS to perfect BMS's rights in such BMS Study Inventions and BMS Study Patent Rights, all at BMS's expense. BMS shall have the sole right but not the obligation to prepare, file, prosecute (including any proceedings relating to reissues, reexaminations, protests, interferences, oppositions, post-grant reviews or similar proceedings and requests for patent extensions) and maintain any BMS Study Patent Rights at its own expense.

(c) Combined Therapy Inventions.

(i) All Combined Therapy Inventions and Combined Therapy Patent Rights shall be jointly owned by the Parties, and either Party shall have the right to freely exploit the Combined Therapy Inventions and Combined Therapy Patent Rights, both within and outside the scope of this Agreement, without accounting or any other obligation to the other Party (except as expressly set forth in this Section 6.1(c) and Section 6.3(d) with regard to the filing, prosecution, maintenance and enforcement of Combined Therapy Patent Rights) and each Party may use, exploit and grant licenses (with right to sublicense) to Third Parties under its interest in such Combined Therapy Inventions and Combined Therapy Patent Rights. The Recipient, using outside counsel acceptable to both Parties, shall be responsible, at its sole discretion, for preparing and prosecuting Patent applications and maintaining Patents within the Combined Therapy Patent Rights. The Recipient shall keep BMS advised as to material developments and steps to be taken with respect to prosecuting any such Patent Rights and shall furnish BMS with copies of applications for such Patent Rights, amendments thereto and other related correspondence to and from patent offices, and permit BMS a reasonable opportunity to review and offer comments prior to submitting such applications and correspondence to the applicable governmental authority (and will take BMS's comments into account in preparing same). BMS shall reasonably assist and cooperate in obtaining, prosecuting and maintaining the Combined Therapy Patent Rights.

(ii) Notwithstanding the foregoing clause (i), the Recipient shall not take any position in a submission to a patent office concerning a Combined Therapy Invention that interprets the scope of a Patent Right of BMS without the prior written consent of BMS, provided that BMS has notified the Recipient in writing of the existence and scope of such BMS Patent Right. The Recipient shall be reimbursed for any costs and expenses incurred in prosecuting Combined Therapy Patent Rights and the subsequent maintenance of Combined Therapy Patent Rights by BMS such that BMS shall be responsible for [*******] of such costs. From time-to-time, the Recipient shall invoice BMS such amounts and BMS shall pay the Recipient such invoiced amounts within thirty (30) days after receipt of an invoice therefor.

(iii) The Parties shall discuss in good faith the countries in which the Combined Therapy Patent Rights will be filed. In case one of the two Parties decides that Combined Therapy Patent Right should not be filed or maintained in a given country (and also elects not to reimburse the other Party for [***] of the costs of prosecution and maintenance of such Combined Therapy Patent Right in such country), the other Party shall have the right to file, prosecute and maintain such Combined Therapy Patent Right in such country in its own name and at its own expense upon the prior consent of the other Party, which shall not be unreasonably withheld, conditioned or delayed. In this case, the Party who decides that a Combined Therapy Patent Right should not be filed or maintained (and who also decides not to reimburse the other Party for its share of the costs of for a given country shall promptly assign its rights to the Combined Therapy Patent Right in said country to the Party (the "***Filing Party***") who wishes to file or maintain said Combined Therapy Patent Right in such country and the Filing Party shall grant, and hereby grants, to the other Party an irrevocable, perpetual, fully-paid, non-exclusive license, with the right to grant and authorize sublicenses, under such Combined Therapy Patent Rights to make, have made, use, sell, offer for sale, import and other exploit products and services in such country. The Party who does not wish to file or maintain a Combined Therapy Patent Right in any country shall assist in the timely provision of all documents required under national provisions to register said assignment of rights with the corresponding national authorities at the sole expenses of the Party who wishes to file or maintain such Combined Therapy Patent Right in that given country. If the Parties cannot agree with respect to the decision to file or maintain a Combined Therapy Patent Right within [***] subsequent to the initiation of the Parties' good faith efforts to resolve any disagreement, then either Party (whichever files first) shall have the right to file or maintain any Combined Therapy Patent Right in the names of both Parties, provided that: (i) any such Combined Therapy Patent Right shall be jointly owned by the Parties and subject to the freedom to use and operate under such Combined Therapy Patent Right as set forth in the first sentence of this Section 6.1(c); (ii) such prosecuting Party obtains the prior consent of the non-prosecuting Party, which consent shall not be unreasonably withheld or delayed, and (iii) the non-prosecuting party reimburses the prosecuting party for its [***] share of the patent costs.

(d) Separation of Patent Rights. In order to more efficiently enable the prosecution and maintenance of the BMS Study Patent Rights, the Recipient Study Patent Rights and Combined Therapy Patent Rights relating to Inventions as described above, the Parties will use good faith efforts to separate BMS Study Patent Rights, the Recipient Study Patent Rights, Combined Therapy Patent Rights, BMS Independent Patent Rights and the Recipient Independent Patent Rights into separate patent filings to the extent possible and without adversely impacting such prosecution and maintenance or the scope of the protected subject matter.

6.2 Disclosure and Assignment of Inventions; Ownership of Independent Patent Rights. Each Party shall disclose promptly to the other Party in writing and on a confidential basis all Inventions, prior to any public disclosure thereof or filing of Patent Rights therefor and allowing sufficient time for comment by the other Party. In addition, each Party shall, and does hereby, assign, and shall cause its Affiliates and contractors to so assign, to the other Party, without additional compensation, such right, title and interest in and to any Inventions as well as any Patent Rights and other intellectual property rights with respect thereto, as is necessary to fully effect, as applicable, the sole ownership provided for in Sections 6.1(a) and 6.1(b) and the joint ownership provided for in Section 6.1(c). Each Party shall ensure that each of its employees and contractors conducting activities under this Agreement is under written obligation to assign all right, title and interest in and to all Inventions and Study Data and all intellectual property rights therein to such Party. Except for the license granted in Section 3.1, nothing in this Agreement shall be construed to grant or transfer to Recipient any rights in the BMS Independent Patent Rights, which shall be the sole and exclusive property of BMS, and nothing in this Agreement shall be construed to grant or transfer to BMS any rights in the Recipient Independent Patent Rights, all of which shall be the sole and exclusive property of Recipient.

6.3 Infringement of Patent Rights by Third Parties.

(a) Notice. Each Party shall promptly notify the other Party in writing of any Infringement of Combined Therapy Patent Rights, of which its in-house patent counsel becomes aware.

(b) Infringement of Recipient Study Patent Rights. For all Infringements of Recipient Study Patent Rights anywhere in the world, the Recipient shall have the exclusive right to prosecute such Infringements as it may determine in its sole and absolute discretion, and the Recipient shall bear all related expenses and retain all related recoveries. BMS shall reasonably cooperate with the Recipient or its designee (to the extent BMS has relevant information arising out of this Agreement), at the Recipient's request and expense, in any such action.

(c) Infringement of BMS Study Patent Rights. For all Infringements of BMS Study Patent Rights anywhere in the world, BMS shall have the exclusive right to prosecute such Infringements as it may determine in its sole and absolute discretion, and BMS shall bear all related expenses and retain all related recoveries. The Recipient shall reasonably cooperate with BMS or its designee (to the extent that the Recipient has relevant information arising out of this Agreement), at BMS's request and expense, in any such action.

(d) Infringement of Combined Therapy Patent Rights.

(i) With respect to Infringements of Combined Therapy Patent Rights, the Parties shall mutually agree as to whether to bring an enforcement action to seek the removal or prevention of such Infringements and damages therefor and, if so, which Party shall bring such action, with any costs and expenses relating thereto to be allocated in accordance with Section 6.3(d)(ii).

(ii) Regardless of which Party brings an enforcement action pursuant to Section 6.3(d)(i) or whether the Parties reach agreement to initiate such an enforcement action, the other Party hereby agrees to cooperate reasonably in any such action, including, if required, by bringing a legal action, furnishing a power of attorney or jointing as a plaintiff to such a legal action. If the Parties mutually agree to bring an enforcement action, BMS shall be responsible for [*******], and the Recipient shall be responsible for [*******], of the reasonable and verifiable costs and expenses incurred in connection with any such action. If either Party recovers monetary damages from any Third Party in an action agreed to by the Parties, such recovery shall be allocated first to the reimbursement of any actual,

unreimbursed costs and expenses incurred by the Parties in such litigation (including, for this purpose, a reasonable allocation of expenses of internal counsel) pro rata in accordance with the aggregate amounts spent by both Parties, and any remaining amounts shall be split [*******] to the Recipient and [*******] to BMS, unless the Parties agree in writing to a different allocation. If the Parties do not agree to initiating such an enforcement action, (A) the Party initiating such enforcement action shall be responsible for the costs and expenses incurred in connection with such action and shall reimburse the other Party for the costs the other Party incurs for the assistance and cooperation requested by such Party and (B) the Party initiating such enforcement action shall retain all recoveries from such enforcement action. In connection with any proceeding under this Section 6.3(d), neither Party shall enter into any settlement without the prior written consent of the other Party.

6.4 Infringement of Third Party Rights.

(a) Notice. If the activities relating to the Combined Therapy Clinical Trial become the subject of a claim of infringement of a patent, copyright or other proprietary right by a Third Party anywhere in the world, the Party first having notice of the claim shall promptly notify the other Party and, without regard to which Party is charged with said infringement and the venue of such claim, the Parties shall promptly confer to discuss the claim.

(b) Defense. If both Parties are charged with infringement pursuant to a claim described in Section 6.4(a), each Party shall have the right to defend itself against such claim and the Parties shall discuss in good faith defending such claim jointly. If only one Party is charged with infringement, such Party will have the first right but not the obligation to defend such claim. If the charged Party does not commence actions to defend such claim within thirty (30) calendar days after request by the other Party to do so, then the other Party shall have the right, but not the obligation, to defend any such claim to the extent such claim pertains to the other Party's Compound. In any event, the non-defending Party shall reasonably cooperate with the Party conducting the defense of the claim and shall have the right to participate with separate counsel at its own expense, and the defending Party shall consider comments and suggestions on strategy for defending the action by the non-defending Party in good faith. The Party defending the claim shall bear the cost and expenses of the defense of any such

Third Party infringement claim and shall have sole rights to any recovery. If the Parties jointly defend the claim, the Recipient shall bear [***], and BMS shall bear [***] of any costs and expenses of the defense of any such Third Party infringement claim; *provided, however, that*, notwithstanding the foregoing, if the claim relates solely to one Party's Compound, such Party will bear one hundred percent (100%) of the costs and expenses of the defense of such claim and shall have the sole right, but not the obligation, to defend, settle and otherwise handle the disposition of such claim. Neither Party shall enter into any settlement concerning activities under this Agreement or the Combined Therapy that affects the other Party's rights under this Agreement or imposes any obligations on the other Party, including any admissions of wrongdoing on behalf of the other Party, without such other Party's prior written consent, not to be unreasonably withheld or delayed, except that a Party may settle any claim that solely relates to its Compound without the consent of the other Party as long as such other Party's rights under this Agreement are not adversely impacted (in which case, it will obtain such other Party's prior written consent, not to be unreasonably withheld or delayed). If any claim described in this Section 6.4(b) is subject to a Party's indemnification obligations under Article 11, then Article 11 shall govern such claim and not this Section 6.4(b).

6.5 Combined Therapy Clinical Trial Regulatory Documentation. Subject to the license and other rights granted by each Party to the other Party pursuant to this Agreement, the Recipient shall solely own all right, title and interest in and to the Combined Therapy Clinical Trial Regulatory Documentation; *provided*, *however*, *that* BMS shall retain sole and exclusive ownership of any BMS Regulatory Documentation that is submitted with or referenced in the Combined Therapy Clinical Trial Regulatory Documentation and that the Recipient shall retain sole and exclusive ownership of any Recipient Regulatory Documentation that is submitted with or referenced in the Combined Therapy Clinical Trial Regulatory Documentation. This Section 6.5 is without limitation of any other disclosure obligations under this Agreement.

6.6 No Other Use. Except as expressly provided in Section 6.1, the Recipient agrees not to make or file any Patent Rights application based on or containing BMS Confidential Information, and to give no assistance to any Third Party for such application without BMS's prior written authorization, and BMS agrees not to make or file any Patent Rights application based on or containing the Recipient's Confidential Information, and to give no assistance to any Third Party for such application without the Recipient's prior written authorization.

6.7 Joint Research Agreement. The Parties acknowledge and agree that this Agreement is a "joint research agreement" as defined in 35 USC § 100 (h).

ARTICLE 7

COSTS AND EXPENSES

7.1 Manufacturing and IP Costs. Expenses incurred as described in Article 4 (regarding Manufacturing and Supply) and Article 6 (regarding Intellectual Property) shall be borne or shared by the Parties as provided in such Articles.

7.2 TP Study Costs. For all expenses (other than those set forth in section 7.1) that are directly attributable or reasonably allocable to the conduct of the Combined Therapy Clinical Trial: (a) the Recipient will solely bear all out-of-pocket costs reasonably incurred by the Recipient (or by BMS pursuant to the following sentence) to Third Parties (including to CROs, laboratories and clinical sites/IRBs) in connection with the performance of the Combined Therapy Clinical Trial ("***TP Study Costs***"), and (b) each Party shall be solely responsible for all of its own internal costs (including costs of individual independent contractors) incurred by such Party or any of its Affiliates. It is not expected that BMS will incur any TP Study Costs; however, in the event BMS should incur any TP Study Costs in connection with the conduct of the Combined Therapy Clinical Trial as contemplated by the budget therefor or as previously agreed to in writing by the Parties, the Recipient will reimburse BMS for same on a [***] following submission of an invoice therefor and appropriate supporting documentation.

7.3 Third Party License Payments. If the conduct of the Combined Therapy Clinical Trial requires a Third Party License Payment with respect to the manufacture, supply and use of the BMS Study Drug used in the Combined Therapy Clinical Trial, then BMS shall be responsible for the payment of any such Third Party License Payment. If the conduct of the Combined Therapy Clinical Trial requires a Third Party License Payment with respect to the manufacture, supply and use of the Recipient Study Drug used in the Combined Therapy Clinical Trial, then Recipient shall be responsible for the payment of any such Third Party License Payment.

ARTICLE 8

RECORDS AND STUDY DATA

8.1 Records. Each Party shall maintain complete and accurate records of all work conducted with respect to the Combined Therapy Clinical Trial and of all results, information, data, data analyses, reports, records, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences and developments made by or provided to either Party, or by the Parties together, in the course of such Party(ies)' efforts with respect to the Combined Therapy Clinical Trial (including any statistical analysis plan and any bioanalysis plan to be conducted pursuant to the Protocol or otherwise agreed to by the Parties) (such results, information, data, data analyses, reports, case report forms, adverse event reports, trial records, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, developments, and the Protocol referred to as the "***Study Data***"). Such records shall fully and properly reflect all work done and results achieved in the performance of the Combined Therapy Clinical Trial in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes.

8.2 Ownership of Study Data. BMS shall own the Study Data to the extent that it relates exclusively to the BMS Study Drug ("***BMS Study Data***"), and the Recipient shall own the Study Data to the extent that it relates exclusively to the Recipient Study Drug ("***Recipient Study Data***"). Both Parties shall jointly own any Study Data that does not relate exclusively to the Recipient Study Drug or the BMS Study Drug ("***Combined Therapy Study Data***"). Each Party shall, and does hereby, assign, and shall cause its Affiliates to so assign, to the other Party, without additional compensation, such right, title and interest in and to any Study Data as is necessary to fully effect the foregoing, and agrees to execute all instruments as may be reasonably necessary to effect same.

8.3 Use of Study Data.

(a) Use of a Party's Own Study Data. BMS may use and analyze the BMS Study Data for any purpose without obligation or accounting to the Recipient, who shall hold the BMS Study Data in confidence pursuant to this Agreement. The Recipient may use and analyze the

Recipient Study Data for any purpose without obligation or accounting to BMS, who shall hold the Recipient Study Data in confidence pursuant to this Agreement.

(b) Use of Combined Therapy Study Data by BMS. BMS, Ono and their respective Affiliates and (sub)licensees shall have the right to use and analyze the Combined Therapy Study Data (i) in connection with the independent development, commercialization or other exploitation of the BMS Study Drug (alone or in combination with other drugs and/or other pharmaceutical agents) and/or for inclusion in the safety database for the BMS Study Drug, in each case without the consent of, or any obligation to account to, the Recipient, and (ii) to conduct studies with Samples pursuant to Section 8.5. Subject to Section 8.5, the results of all such analyses or uses shall be owned by BMS, including any intellectual property arising out of same, unless the Parties shall have agreed otherwise in a writing separate from this Agreement. BMS, Ono, and their respective Affiliates and (sub)licensees shall also be entitled to use the Combined Therapy Study Data during and following the Term to (1) make regulatory filings, meet regulatory requirements, and seek approvals for the BMS Study Drug, either alone or as part of the Combined Therapy, (2) evaluate the safety and efficacy of the Combined Therapy and the BMS Study Drug, (3) promote indications based on, and to disseminate, the Combined Therapy Study Data for the benefit of the BMS Study Drug, either alone or as part of the Combined Therapy, where permitted by and in accordance with Applicable Law; *provided that* nothing in the foregoing is intended or shall be construed as granting BMS any right or license, expressly or impliedly to make, have made, use, sell, offer for sale, or import the Recipient Study Drug; and (4) include in Patent Rights filings made in the course of

the prosecution of BMS Independent Patent Rights that do not Cover both the composition of matter of the Recipient Study Drug, its manufacture or formulation, method of use and the BMS Study Drug. The Recipient grants BMS, Ono, their respective Affiliates and (sub)licensees (of rights to the BMS Study Drug) a Right of Cross-Reference to the Recipient Regulatory Documentation Controlled by Recipient for the Recipient Study Drug and the Combined Therapy Clinical Trial Regulatory Documentation for the Recipient Study Drug or the Combined Therapy for the sole purpose of enabling BMS, Ono and their Affiliates and sublicensees to exercise its rights under clause (1) of this Section 8.3(b), which right shall survive any expiration or termination of this Agreement.

(c) Use of Combined Therapy Study Data by the Recipient. The Recipient and its Affiliates and licensees shall have the right to use and analyze the Combined Therapy Study Data (i) in connection with the independent development, commercialization or other exploitation of the Recipient Study Drug (alone or in combination with other drugs and/or other pharmaceutical agents) and/or for inclusion in the safety database for the Recipient Study Drug, in each case without the consent of, or any obligation to account to, BMS and (ii) to conduct studies with Samples pursuant to Section 8.5. Subject to Section 8.5, the results of all such analyses or uses shall be owned by the Recipient, including any intellectual property arising out of same, unless the Parties shall have agreed otherwise in writing separate from this Agreement. The Recipient, its Affiliates and (sub)licensees shall be entitled to use the Combined Therapy Study Data during and following the Term to (1) make regulatory filings, meet regulatory requirements and seek approvals for the Recipient Study Drug, either alone or as part of the Combined Therapy, (2) evaluate the safety and efficacy of the Combined Therapy and the Recipient Study Drug, (3) promote indications based on, and to disseminate, the Combined Therapy Study Data for the benefit of the Recipient Study Drug, either alone or as part of the Combined Therapy, where permitted by and in accordance with Applicable Law; *provided that* nothing in the foregoing is intended or shall be construed as granting the Recipient any right or license, expressly or impliedly, to make, have made, use, sell, offer for sale, or import the BMS Study Drug; and (4) and include in Patent Rights filings made in the course of the prosecution of Recipient Independent Patent Rights that do not Cover both the composition of matter of the BMS Study Drug, its manufacture or formulation, method of use and the Recipient Study Drug. BMS grants the Recipient, its Affiliates and licensees of the Recipient Study Drug a Right of Cross-Reference to the relevant Regulatory Documentation Controlled by BMS for the BMS Study Drug for the sole purpose of enabling the Recipient, its Affiliates and (sub)licensees to exercise its rights under clause (1) of this Section 8.3(c) (for clarity, such Right of Cross-Reference shall not extend to any Ono-controlled Regulatory Documentation) in all countries and territories of the world, which right shall survive any expiration or termination of this Agreement.

(d) Biomarker/Dx Agent Development. Each Party may use and disclose to a Third Party the Combined Therapy Study Data and its Compound's Study Data, under obligations of confidentiality consistent with this Agreement, to develop and commercialize a biomarker or diagnostic test for use with its Compound (including without limitation another combination therapy involving its Compound) and/or the Combined Therapy, and, unless otherwise mutually agreed by the Parties in writing, will own any intellectual property arising out of the work funded or conducted by it with or through such Third Party. Each Party shall grant, and hereby grants, to the other Party a worldwide, perpetual, irrevocable, fully paid-up, royalty-free non-exclusive license, with the right to grant and authorize sublicenses, under such intellectual property and data to develop and commercialize biomarkers and/or diagnostic tests for use with the Combined Therapy. The Parties will discuss in good faith any opportunities to jointly participate in the development of any such biomarker or diagnostic test for use with the Combined Therapy.

(e) No Other Uses. All other uses of Combined Therapy Study Data (by either Party), Recipient Study Data (by BMS) and BMS Study Data (by the Recipient) are limited solely to those permitted by this Agreement, and neither Party may use such Study Data for any other purpose without the consent of the other Party during and after the Term.

8.4 Access to Study Data. Subject to the provisions of Sections 8.1, each Party shall have access to all Combined Therapy Study Data, Recipient Study Data and BMS Study Data (including de-identified patient records). The relevant Party shall make such Study Data in its possession available to the

other Party within a reasonable period, not to exceed [***], after such Study Data is available to or generated by the applicable Party.

8.5 Samples.

(a) Samples shall be jointly owned by the Parties (to the extent not owned by the patient and/or the clinical trial site). Any such Samples shall be collected in accordance with the Protocol and applicable ICFs. Except as set forth in the Protocol, neither Party shall be permitted to use such Samples for any purpose without the prior written consent of the other Party, which consent shall not be unreasonably withheld if such use is directed to the Combined Therapy and with the terms of such use to be set forth in a written agreement between the Parties setting forth the Samples to be used, and any appropriate terms/restrictions on such use. For clarity, Replimune shall have the right, without further consent of BMS, to use and study any such Samples as set forth in the Protocol, it being understood that if the Protocol does not reference specific assays to be utilized in the analysis of any such Samples and such analysis will be in the discretion of Replimune. Except for intellectual property pertaining solely to the [***] (which shall be owned by BMS), any data and intellectual property arising out of such Sample use shall be owned by the Party conducting such study using same, *provided that*, to the extent that any such data or intellectual property relates solely to the Combined Therapy (or biomarkers solely for use with the Combined Therapy), shall be considered Combined Therapy Study Data, Combined Therapy Inventions and/or Combined Therapy Patent Rights, as the case may be. All Samples, including Samples for PK and ADA serum analysis will be stored for future use in the Recipient's sample repository, unless the Parties mutually agree that BMS would store such samples, *provided that*, if the Party holding the Samples determines that it no longer has a use for the Samples and the other Party determines that it does, then the Samples shall, subject to Applicable Law and the terms of the signed ICFs, be transferred to the other Party and may be used solely thereafter by the other Party. If neither Party has any further use for the Samples, then the remaining Samples will be destroyed pursuant to the respective Party's standard operating procedures for sample retention and destruction, subject to the terms of and permission(s) granted in the informed consent forms signed by the subjects contributing the Samples in the Combined Therapy Clinical Trial.

(b) If required by a Regulatory Authority or necessary as part of the Protocol or related bioanalysis plan, BMS will arrange for the Recipient to use BMS's preferred Third Party vendor(s), at the Recipient's expense, for bioanalytical work of Samples from Combined Therapy Clinical Trial subjects on the BMS Study Drug. Such vendor(s) will provide the results of their bioanalytical work of such Samples to the Recipient and BMS, which results will be included in the final clinical study report, along with the bioanalytical work of the Recipient Study Drug and BMS Study Drug performed by or on behalf of the Recipient. For the avoidance of doubt, all bioanalytical results for the BMS Study Drug and the Recipient Study Drug are deemed Study Data. All data derived pursuant to the Protocol from such Samples is deemed Study Data.

ARTICLE 9

CONFIDENTIALITY

9.1 Nondisclosure of Confidential Information.

(a) Any Confidential Information relating to the BMS Study Drug (in connection with the Combined Therapy Clinical Trial), Recipient Study Drug or the conduct of the Combined Therapy Clinical Trial previously disclosed by the Parties pursuant to the RP-1 Agreement shall now be Confidential Information for purposes of this Agreement and the Parties shall treat it as such in accordance with the terms hereof. All written, visual, oral and electronic data, information, know-how or other proprietary information or materials, both technical and non-technical, disclosed by one Party to the other Party pursuant to this Agreement, and disclosed in the manner specified herein, that (a) if in tangible form, is labeled in writing as "proprietary" or "confidential" (or similar reference), or (b) if in oral or visual form, is identified as proprietary or confidential or for internal use only at the time of disclosure or within thirty (30) calendar days thereafter shall be "***Confidential Information***" of the disclosing Party, and all Study Data and Inventions shall be the Confidential Information of the Party (or Parties) owning such Study Data or

Invention (as provided in Section 8.2 with regard to Study Data and Section 6.1 with regard to Inventions). For purposes of this Agreement, regardless of which Party discloses such Confidential Information to the other, (i) all Recipient Study Inventions, Recipient Technology and Recipient Regulatory Documentation shall be Confidential Information of the Recipient and BMS shall be the receiving Party, and (ii) all BMS Study Inventions, BMS Technology, and BMS Regulatory Documentation shall be Confidential Information of BMS and the Recipient shall be the receiving Party.

(b) The Parties agree that the terms of this Agreement shall be treated as Confidential Information of both Parties, and thus may be disclosed only as permitted by Section 9.3. Except as required by Applicable Law, each Party agrees not to issue any press release or public statement disclosing information relating to this Agreement or the transactions contemplated hereby or the terms hereof without the prior written consent of the other Party, except as permitted by Sections 9.3 and 9.6(b).

(c) Except to the extent expressly authorized in this Section 9.1 and Sections 9.2, 9.3 and 9.6 below, or as otherwise agreed in writing by the Parties, each Party agrees that, for the Term and for a period of [*******] thereafter, it shall (A) keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as expressly provided for in this Agreement any Confidential Information of the other Party (including information relating to this Agreement or the transactions contemplated hereby or the terms hereof), (B) treat the other Party's Confidential Information with the same degree of care the receiving Party uses for its own confidential information but in no event with less than a reasonable degree of care; and (C) reproduce the disclosing Party's Confidential Information solely to the extent necessary or reasonably useful to accomplish the receiving Party's obligations under this Agreement or exercise the receiving Party's rights to use and disclose such Confidential Information as expressly provided for in this Agreement, with all such reproductions being considered the disclosing Party's Confidential Information, *provided that*, with respect to BMS Confidential Information that was received as confidential information from Ono, the obligations of confidentiality and nonuse shall continue until BMS has obtained Ono's written consent that the same may be freely used. Notwithstanding anything to the contrary in this Section 9.1, and subject to Section 8.3, the receiving Party may disclose the disclosing Party's Confidential Information to its employees, consultants, agents or permitted (sub)licensees solely on a need-to-know basis for the purpose of fulfilling the receiving Party's obligations under this Agreement or exercising the receiving Party's rights to use and disclose such Confidential Information as expressly provided for in this Agreement; *provided, however, that* (1) any such employees, consultants, agents or permitted (sub)licensees are bound by obligations of confidentiality and non-use at least as restrictive as those set forth in this Agreement, and (2) the receiving Party remains liable for the compliance of such employees, consultants, agents or permitted (sub)licensees with such obligations. Each receiving Party acknowledges that in connection with its and its representatives examination of the Confidential Information of the disclosing Party, the receiving Party and its representatives may have access to material, non-public information, and that the receiving Party is aware, and will advise its representatives who are informed as to the matters that are the subject of this Agreement, that State and Federal laws, including United States securities laws, may impose restrictions on the dissemination of such information and trading in securities when in possession of such information. Each receiving Party agrees that it will not, and will advise its representatives who are informed as to the matters that are the subject of this Agreement to not, purchase or sell any security of the disclosing Party on the basis of the Confidential Information to the extent such Confidential Information constitute material nonpublic information about the disclosing Party or such security.

(d) Combined Therapy Study Data shall be treated as Confidential Information of each Party and shall not be disclosed to Third Parties except to the extent it falls within the exceptions set forth in Section 9.2 below, is authorized under this Section 9.1 or Section 9.3, is required to be filed with a Regulatory Authority or included in a product's label or package insert, is reasonably necessary to be disclosed in order for a Party to exercise its rights under Section 8.3(b) or 8.3(c) or it is disclosed pursuant to Section 9.5.

9.2 Exceptions. The obligations in Section 9.1 shall not apply with respect to any portion of Confidential Information that the receiving Party can demonstrate by contemporaneous tangible records or other competent proof:

(a) was already known to the receiving Party (or its Affiliates), other than under an obligation of confidentiality, either (i) at the time of disclosure by the disclosing Party, or (ii) if applicable, at the time that it was generated hereunder, whichever ((i) or (ii)) is earlier;

(b) was generally available to the public or otherwise part of the public domain either (i) at the time of its disclosure to the receiving Party, or (ii) if applicable, at the time that it was generated hereunder, whichever ((i) or (ii)) is earlier;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;

(d) was disclosed to the receiving Party (or its Affiliates), other than under an obligation of confidentiality, by a Third Party who had no obligation to the Party owning or Controlling the information not to disclose such information to others; or

(e) was independently discovered or developed by the receiving Party (or its Affiliates) without the use of, or reference to, the Confidential Information belonging to the disclosing Party.

9.3 Authorized Disclosure. Notwithstanding any other provision of this Agreement, each Party may disclose Confidential Information belonging to the other Party to the extent such disclosure is reasonably necessary in the following instances:

(a) filing or prosecuting Patent Rights pursuant to Section 6.1(c);

(b) prosecuting or defending litigation;

(c) complying with Applicable Law or the rules or regulations of any securities exchange on which such Party's stock is listed;

(d) disclosure, in connection with the performance of this Agreement, to Affiliates, permitted (sub)licensees, contractors, IRBs, CROs, academic institutions, consultants, agents, investigators, and employees and contractors engaged by study sites and investigators involved with the Combined Therapy Clinical Trial, each of whom prior to disclosure must be bound by terms of confidentiality and non-use at least as protective of Confidential Information as those set forth in this Article 9;

(e) disclosure of the Combined Therapy Study Data, Combined Therapy Inventions and Combined Therapy Patent Rights to Regulatory Authorities in connection with the development and obtaining of regulatory approval of the Combined Therapy, the Recipient Study Drug or the BMS Study Drug;

(f) disclosure of relevant safety information contained within the Combined Therapy Study Data to investigators, IRBs and/or ethics committees and Regulatory Authorities that are involved in other clinical trials of the Recipient Study Drug with respect to the Recipient, and the BMS Study Drug with respect to BMS, and, in the event of a Material Safety Issue, to Third Parties that are collaborating with the Recipient or BMS, respectively in the conduct of such other clinical trials of the Recipient Study Drug or the BMS Study Drug, in each case solely to the extent necessary for the conduct of such clinical trials and/or to comply with Applicable Law and regulatory requirements; and

(g) subject to a [*******] advance written notice to BMS, in communications with [*******], under confidentiality provisions as least as protective of Confidential Information as those of this Agreement; *provided* that with respect to [*******] such disclosure shall be limited to the terms and conditions of this Agreement and the Combined Therapy Study Data.

Notwithstanding the foregoing, if a Party is required or otherwise intends to make a disclosure of any other Party's Confidential Information pursuant to Section 9.3(b) and/or Section 9.3(c), it shall give advance notice to such other Party of such impending disclosure and endeavor in good faith to secure

confidential treatment of such Confidential Information and/or reasonably assist the Party that owns such Confidential Information in seeking a protective order or other confidential treatment.

9.4 Disclosure to Ono. Notwithstanding any other provision of this Agreement, BMS shall be entitled to disclose to Ono (a) the existence (but not the terms) of this Agreement, the Combined Therapy Clinical Trial and the Protocol, and (b) any other Recipient Confidential Information necessary for BMS to fulfill its obligations to Ono under the Ono-BMS Agreements; *provided that* Ono is under confidentiality obligations at least as restrictive as set forth herein. BMS shall be free to disclose to Ono and permit Ono to use the BMS Study Data and the Combined Therapy Study Data as BMS may determine (so long as such use is consistent with BMS's permitted uses under Section 8.3(b)).

9.5 Press Releases and Publications.

(a) The Parties shall jointly agree to the content and timing of all public communications with respect to this Agreement, press releases, Q&As, and the content of, and wording for, any listing of the Combined Therapy Clinical Trial required to be listed on a public database or other public registry such as www.clinicaltrials.gov). For clarity, if either Party terminates this Agreement pursuant to Section 12.4, the Parties shall mutually agree upon any external communication related to such termination, which shall not include the rationale for such termination unless (and to the extent) mutually agreed by the Parties. Notwithstanding the foregoing in this Section 9.5(a), either Party shall be permitted to publicly disclose information that such Party determines in good faith is necessary to be disclosed to comply with Applicable Law or the rules or regulations of any securities exchange on which such Party's stock may be listed, or pursuant to an order of a court or governmental entity.

(b) The Recipient and BMS agree to collaborate to publicly disclose, publish or present (i) top-line results from the Combined Therapy Clinical Trial, limited if possible to avoid jeopardizing the future publication of the Study Data at a scientific conference or in a scientific journal, solely for the purpose of disclosing, as soon as reasonably practicable, the safety or efficacy results and conclusions that are material to either Party under applicable securities laws, and (ii) the conclusions and outcomes (the "***Results***") of the Combined Therapy Clinical Trial at a scientific conference as soon as reasonably practicable following the database lock date for such Combined Therapy Clinical Trial, subject in the case of (ii) to the following terms and conditions. The Party proposing to disclose, publish or present the Results shall deliver to the other Party a copy of the proposed disclosure, publication or presentation at least [*******] before submission to a Third Party. The reviewing Party shall determine whether any of its Confidential Information that may be contained in such disclosure, publication or presentation should be modified or deleted, whether to file a patent application on any Recipient Study Invention (solely with respect to the Recipient) or BMS Study Invention (solely with respect to BMS) or Combined Therapy Invention disclosed therein. The disclosure, publication or presentation shall be delayed for an additional [*******] (i.e., a total of [*******] from the initial proposal) if the reviewing Party reasonably requests such extension to allow time for the preparation and filing of relevant patent applications consistent with the terms of this Agreement. If the reviewing Party reasonably requests modifications to the disclosure, publication or presentation to prevent the disclosure of Confidential Information of the reviewing Party (other than the Results or Study Data), the publishing Party shall edit such publication to prevent the disclosure of such information prior to submission of the disclosure, publication or presentation. In the event of a disagreement as to content, timing and/or venue or forum for any disclosure, publication or presentation of the Results, such dispute (a "***Publication Dispute***") shall be referred to the Executive Officers (or their respective designees); provided that, in the absence of agreement after such good faith discussions, and upon expiration of the additional [*******] period, (A) academic collaborators or clinical trial sites engaged by the Recipient in connection with the performance of the Combined Therapy Clinical Trial may publish Combined Therapy Study Data obtained by such academic collaborator or clinical trial site solely to the extent that such ability to publish such Combined Therapy Study Data is set forth in an agreement between the Recipient and such academic collaborator or clinical trial site relating to the conduct of Combined Therapy Clinical Trial and (B) the publishing Party may proceed with the disclosure, publication or presentation provided that such disclosure, publication or presentation is consistent with its internal publication guidelines and customary industry practices for the publication of similar data and does not disclose the Confidential Information of the other Party (other than the Results or Study Data). Authorship of any publication shall be determined based on the accepted standards used in peer-reviewed academic journals at the time of the proposed disclosure,

publication or presentation. The Parties agree that they shall make reasonable efforts to prevent publication of a press release that could jeopardize the future publication of Study Data at a scientific conference or in a scientific journal but in no way will this or any other provision of this Agreement supersede the requirements of any Applicable Law or the rules or regulations of any securities exchange or listing entity on which a Party's stock is listed (including any such rule or regulation that may require a Party to make public disclosures about interim results of the Combined Therapy Clinical Trial). Notwithstanding the foregoing, nothing herein shall prevent or restrict Ono from making any disclosures of published Study Data disclosed to it by BMS pursuant to Section 9.4 or of the existence of this Agreement, in each case in order for Ono to comply with requirements of Applicable Law, the rules or regulations of any securities exchange or listing entity on which its stock may be traded or pursuant to an order of a court or governmental entity to publicly disclose the existence of the Agreement and the Study Data, provided that if any such disclosure is made by Ono it will only disclose the minimum amount of information necessary to achieve compliance and will provide the Recipient with reasonable advance notice of such disclosure.

(c) The Recipient agrees to include in all permitted press releases, presentations and publications it makes related to the Combined Therapy Clinical Trial specific mention, if applicable, of the BMS Study Drug and the support and involvement of BMS. BMS agrees to include in all permitted press releases, presentations and publications it makes related to the Combined Therapy Clinical Trial specific mention, if applicable, of the Recipient Study Drug and the support and involvement of the Recipient.

9.6 Compliance with Sunshine Laws.

(a) For purposes of compliance with reporting obligations under Sunshine Laws, as between the Parties, the Recipient/the Recipient represents that it is not, as of the Effective Date, subject to reporting obligations under the Sunshine Laws. Therefore, as between the Parties, BMS will report payments or other transfers of value ("***POTV***") made by the Recipient or the CRO related to the conduct of the Combined Therapy Clinical Trial and any applicable associated contractor engagements as required under the Sunshine Laws for the Combined Therapy Clinical Trial. BMS shall request delayed publication for any reported POTV for studies sponsored by the Recipient as permitted under the Sunshine Laws and if consistent with BMS's normal business practices. In the event that the Recipient becomes responsible for reporting POTV for studies sponsored by it in a given country during the Term, the Recipient shall provide written notification to BMS and the Parties will meet to confer to discuss how they wish to handle reporting thereafter. Interpretation of the Sunshine Laws for purposes of reporting any POTV by a Party shall be in such Party's sole discretion so long as the interpretation complies with Applicable Law.

(b) The Recipient (i) will provide (to the extent in the possession of the Recipient), or will utilize Commercially Reasonable Efforts to obligate and ensure that each CRO and other applicable Third Party contractors for the Combined Therapy Clinical Trial provides, BMS with any information requested by BMS as BMS may reasonably determine is necessary for BMS to comply with its reporting obligations under Sunshine Laws (with such amounts paid to, or at the direction of, healthcare providers, teaching hospitals and/or any other persons for whom POTVs must be reported under Sunshine Laws to be reported to BMS within a reasonable time period specified by BMS) and (ii) will reasonably cooperate with, and will utilize Commercially Reasonable Efforts to obligate and ensure that each CRO and other applicable Third Party contractors for the Combined Therapy Clinical Trial reasonably cooperates with, BMS in connection with its compliance with such Sunshine Laws. The form in which the Recipient provides any such information shall be mutually agreed but sufficient to enable BMS to comply with its reporting obligations and BMS may disclose any information that it believes is necessary to comply with Sunshine Laws. Without limiting the foregoing, BMS shall have the right to allocate POTVs in connection with this Agreement in any required reporting under Sunshine Laws in accordance with its normal business practices. These obligations shall survive the expiration and termination of this Agreement to the extent necessary for BMS to comply with Sunshine Laws. The Recipient shall not be required to provide any information to BMS that is subject to disclosure pursuant to the Recipient's own obligations under the Sunshine Laws.

(c) For purposes of this Section 9.7, "***Sunshine Laws***" shall mean Applicable Laws requiring collection, reporting and disclosure of POTVs to certain healthcare providers, entities and

individuals. These Applicable Laws may include relevant provisions of the Patient Protection and Affordable Health Care Act of 2010 and implementing regulations thereunder.

9.7 Destruction of Confidential Information. Upon expiration or termination of the Agreement, the receiving Party shall, upon request by the other Party, immediately destroy or return all of the other Party's Confidential Information relating solely to its Compound as monotherapy (but not to the Combined Therapy or the Combined Therapy Study Data) in its possession; *provided*, *however*, *that* the receiving Party shall be entitled to retain one (1) copy of Confidential Information solely for record-keeping purposes and shall not be required to destroy any Confidential Information required, or reasonably necessary, to be retained for any clinical trial activities that continue after expiration or termination, or off-site computer files created during automatic system back up which are subsequently stored securely by the receiving Party.

9.8 Nonsolicitation of Employees. Each Party agrees that, during the [*******] thereafter, neither it nor any of its Affiliates shall recruit, solicit or induce any employee of the other Party directly involved in the development or other activities conducted by the other Party under this Agreement to terminate his or her employment with such other Party and become employed by or consult for such other Party, whether or not such employee is a full-time employee of such other Party, and whether or not such employment is pursuant to a written agreement or is at-will. For purposes of the foregoing, "recruit", "solicit" or "induce" shall not be deemed to mean (a) circumstances where an employee of one Party initiates contact with the other Party or any of its Affiliates with regard to possible employment, or (b) general solicitations of employment not specifically targeted at employees of a Party or any of its Affiliates, including responses to general advertisements.

ARTICLE 10

REPRESENTATIONS AND WARRANTIES

10.1 Authority and Binding Agreement. Each Party represents and warrants to the other Party that (a) it has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder, (b) it has taken all necessary corporate action on its part required to authorize the execution and delivery of the Agreement and the performance of its obligations hereunder, and (c) the Agreement has been duly executed and delivered on behalf of such Party and constitutes a legal, valid and binding obligation of such Party that is enforceable against it in accordance with its terms subject to bankruptcy, insolvency, reorganization, arrangement, winding-up, moratorium, and similar laws of general application affecting the enforcement of creditors' rights generally, and subject to general equitable principles, including the fact that the availability of equitable remedies, such as injunctive relief or specific performance, is in the discretion of the court.

10.2 No Conflicts. Each Party represents and warrants to the other Party that, to the best of its knowledge, it has not entered as of the Effective Date, and shall not enter, into any agreement with any Third Party that is in conflict with the rights granted to the other Party under this Agreement, and has not taken any action that would in any way prevent it from granting the rights granted to the other Party under this Agreement, or that would otherwise materially conflict with or adversely affect the rights granted to the other Party under this Agreement.

10.3 Litigation. Each Party represents and warrants to the other Party, to the best of its knowledge as of the Effective Date, it is not aware of any pending or threatened litigation (and has not received any communication) that alleges that its activities related to this Agreement have violated, or that by conducting the activities as contemplated in this Agreement it would violate, any of the intellectual property rights of any other Person (after giving effect to the license grants in this Agreement).

10.4 No Adverse Proceedings. Each Party represents and warrants to the other Party that, except as otherwise notified to the other Party, as of the Effective Date, there is not pending or, to the knowledge of such Party, threatened, against such Party, any claim, suit, action or governmental proceeding that would, if adversely determined, materially impair the ability of such Party to perform its obligations under this Agreement.

10.5 Consents. Each Party represents and warrants to the other Party that, to the best of its knowledge, all necessary consents, approvals and authorizations of all regulatory and governmental authorities and other Persons (a) required as of the Effective Date to be obtained by such Party in connection with the execution and delivery of this Agreement have been obtained (or will have been obtained prior to such execution and delivery) and (b) required to be obtained by such Party in connection with the performance of its obligations under this Agreement have been obtained or will be obtained prior to such performance.

10.6 No Debarment. Each Party hereby certifies to the other that it has not used, and will not use the services of any person disqualified, debarred, banned, subject to debarment or convicted of a crime for which a person could be debarred by the FDA under 21 U.S.C. 335a, as amended (or subject to a similar sanction of any other Regulatory Authority), in any capacity in connection with any of the services or work provided under the Combined Therapy Clinical Trial and that this certification may be relied upon in any applications to the FDA or any other Regulatory Authority. It is understood and agreed that this certification imposes a continuing obligation upon each Party to notify the other promptly of any change in the truth of this certification. Upon request by a Party, the other Party agrees to provide a list of persons used to perform the services or work provided under any activities conducted for or on behalf of such Party or any of its Affiliates pursuant to this Agreement who, within the five (5) years preceding the Effective Date, or subsequent to the Effective Date, were or are convicted of one of the criminal offenses required by 21 U.S.C. 335a, as amended, to be listed in any application for approval of an abbreviated application for drug approval.

10.7 Compliance with Applicable Law. Each Party represents and warrants to the other Party that it shall comply with all Applicable Law of the country or other jurisdiction, or any court or agency thereof, applicable to the performance of its activities hereunder or any obligation or transaction hereunder, including those pertaining to the production and handling of drug products, such as those set forth by the Regulatory Authorities, as applicable, and the applicable terms of this Agreement in the performance of its obligations hereunder.

10.8 Affiliates. Each Party represents and warrants to the other Party that, to the extent the intellectual property, Regulatory Documentation or Technology licensed by it hereunder are Controlled by its Affiliates or a Third Party, it has the right to use, and has the right to grant (sub)licenses to the other Party to use, such intellectual property, Regulatory Documentation or Technology in accordance with the terms of this Agreement.

10.9 Ethical Business Practices. Each Party represents and warrants to the other Party that neither it nor its Affiliates will make any payment, either directly or indirectly, of money or other assets, including the compensation such Party derives from this Agreement (collectively a "***Payment***"), to government or political party officials, officials of International Public Organizations, candidates for public office, or representatives of other businesses or persons acting on behalf of any of the foregoing (collectively "***Officials***") where such Payment would constitute violation of any law, including the Foreign Corrupt Practices Act of 1977, 15 U.S.C. §§ 78dd-1, et seq. In addition, regardless of legality, neither it nor its Affiliates will make any Payment either directly or indirectly to Officials if such Payment is for the purpose of improperly influencing decisions or actions with respect to the subject matter of this Agreement. All activities will be conducted in compliance with the U.S. False Claims Act and the U.S. Anti-Kickback Statute.

10.10 Accounting. Each Party represents and warrants to the other Party that all transactions under the Agreement shall be properly and accurately recorded in all material respects on its books and records and that each document upon which entries in such books and records are based is complete and accurate in all material respects.

10.11 Single Agent Compound Safety Issues. Each Party represents and warrants that, to the best of its knowledge as of the Effective Date, it is not aware of any material safety or toxicity issues with respect to its Single Agent Compound that are not reflected in the investigator's brochure for its Single Agent Compound existing as of the Effective Date.

10.12 Compliance with Licensor Agreements. Each Party will use, and will cause its Affiliates to use, Commercially Reasonable Efforts to comply with its obligations under any agreements entered into by it or its Affiliates with a Third Party under which it is licensed any intellectual property rights or confidential information relating to a Compound (and not to voluntarily terminate same) to the extent necessary for the Combined Therapy Clinical Trial to be conducted and completed in accordance with the terms of this Agreement and for the other Party to receive the rights and benefits provided to it under this Agreement.

10.13 DISCLAIMER OF WARRANTY. THE EXPRESS REPRESENTATIONS AND WARRANTIES STATED IN THIS ARTICLE 10 ARE IN LIEU OF, AND THE PARTIES DO HEREBY DISCLAIM, ALL OTHER REPRESENTATIONS AND WARRANTIES, EXPRESS, IMPLIED OR STATUTORY, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR USE, AND NON-INFRINGEMENT OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS.

ARTICLE 11

INDEMNIFICATION

11.1 BMS Indemnification. BMS hereby agrees to defend, hold harmless and indemnify (collectively, "***Indemnify***") the Recipient, its Affiliates, and its and their agents, directors, officers, employees and subcontractors (the "***Recipient Indemnitees***") from and against any and all liabilities, expenses and/or losses, including reasonable legal expenses and attorneys' fees (collectively "***Losses***") resulting from Third Party suits, claims, actions and demands (each, a "***Third Party Claim***") to the extent that they arise or result from (a) the negligence or intentional misconduct of any BMS Indemnitee or any (sub)licensee of BMS conducting activities on behalf of BMS under this Agreement, (b) any breach by BMS of any provision of this Agreement, (c) any injury (other than resulting from known adverse effects) to a subject in the Combined Therapy Clinical Trial to the extent caused by the BMS Study Drug, or (d) the use by BMS, its Affiliates, contractors or (sub)licensees of Combined Therapy Study Data, BMS Study Data, BMS Study Inventions, BMS Study Patent Rights, Combined Therapy Inventions and Combined Therapy Patent Rights (other than with respect to Third Party Claims that are covered under Section 6.4); but excluding, in each case ((a) through (d)), any such Losses to the extent arising or resulting from a cause or event for which the Recipient is obligated to Indemnify the BMS Indemnitees pursuant to Section 11.2.

11.2 Recipient Indemnification. The Recipient hereby agrees to Indemnify BMS, its Affiliates, and its and their agents, directors, officers, employees and subcontractors (the "***BMS Indemnitees***") from and against any and all Losses resulting from Third Party Claims to the extent that they arise or result from (a) the negligence or intentional misconduct of any Recipient Indemnitee or any (sub)licensee of the Recipient conducting activities on behalf of the Recipient under this Agreement, (b) any breach by the Recipient of any provision of this Agreement, (c) any injury to a subject in the Combined Therapy Clinical Trial not caused by the BMS Study Drug, or (d) the use by the Recipient, its Affiliates, contractors or (sub)licensees of Combined Therapy Study Data, Recipient Study Data, Recipient Study Inventions, Recipient Study Patent Rights, Combined Therapy Inventions and

Combined Therapy Patent Rights (other than with respect to Third Party Claims that are covered under Section 6.4); but excluding, in each case ((a) through (d)), any such Losses to the extent arising or resulting from a cause or event for which BMS is obligated to Indemnify the Recipient Indemnitees pursuant to Section 11.1.

11.3 Indemnification Procedure. Each Party's agreement to Indemnify the other Party is conditioned on the performance of the following by the Party seeking indemnification: (a) providing written notice to the Indemnifying Party of any Loss and/or Third Party Claim of the types set forth in Section 11.1 and 11.2 promptly, and in any event within sixty (60) calendar days, after the Party seeking indemnification has knowledge of such Loss and/or Third Party Claim; *provided that*, any delay in complying with the requirements of this clause (a) will only limit the Indemnifying Party's obligation to the extent of the prejudice caused to the Indemnifying Party by such delay, (b) permitting the Indemnifying Party to assume full responsibility to investigate, prepare for and defend against any such Loss and/or Third Party Claim, (c) providing reasonable assistance to the Indemnifying Party, at the Indemnifying Party's expense, in the

investigation of, preparation for and defense of any Loss and/or Third Party Claim, and (d) not compromising or settling such Loss and/or Third Party Claim without the Indemnifying Party's written consent, such consent not to be unreasonably withheld or delayed.

11.4 Separate Defense of Claims. In the event that the Parties cannot agree as to the application of Sections 11.1 and/or 11.2 to any particular Loss, the Parties may conduct separate defenses of such Loss. Each Party further reserves the right to claim indemnity from the other in accordance with Sections 11.1 and/or 11.2 upon resolution of the underlying claim, notwithstanding the provisions of Section 11.3(b).

11.5 Insurance. Each Party shall maintain commercially reasonable levels of insurance or other adequate and commercially reasonable forms of protection or self-insurance to satisfy its indemnification obligations under this Agreement. Each Party shall provide the other Party with written notice at least thirty (30) calendar days prior to the cancellation, non-renewal or material change in such insurance or self-insurance which would materially adversely affect the rights of the other Party hereunder. The maintenance of any insurance shall not constitute any limit or restriction on damages available to a Party under this Agreement.

11.6 LIMITATION OF LIABILITY. NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR INDIRECT, INCIDENTAL, CONSEQUENTIAL OR SPECIAL DAMAGES, INCLUDING LOST PROFITS, ARISING FROM OR RELATING TO THIS AGREEMENT AND/OR SUCH PARTY'S PERFORMANCE HEREUNDER, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES AND REGARDLESS OF THE CAUSE OF ACTION (WHETHER IN CONTRACT, TORT, BREACH OF WARRANTY OR OTHERWISE). NOTHING IN THIS SECTION 11.6 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF A PARTY UNDER SECTIONS 11.1 OR 11.2 IN RELATION TO, OR DAMAGES AVAILABLE FOR, BREACHES OF CONFIDENTIALITY OBLIGATIONS IN ARTICLE 9 OR FOR A PARTY'S GROSS NEGLIGENCE OR WILLFUL MISCONDUCT.

ARTICLE 12

TERM AND TERMINATION

12.1 Term. This Agreement shall be effective as of the Effective Date and, unless earlier terminated pursuant to this Section 12.1, Sections 12.2, 12.3 or 12.4 or any other termination right expressly stated in this Agreement, shall continue in effect until completion of the Combined Therapy Clinical Trial by all centers participating in the Combined Therapy Clinical Trial, delivery of all Study Data, including all completed case report forms, all final analyses and all final clinical study reports contemplated by the Combined Therapy Clinical Trial to both Parties, and the completion of any statistical analyses and bioanalyses contemplated by the Protocol or otherwise agreed to by the Parties to be conducted under this Agreement (the "***Term***"). Notwithstanding the foregoing, either Party shall have the right to immediately terminate this Agreement if the Parties do not agree to a draft Protocol pursuant to Section 2.1(a) within [***] after the Effective Date on written notice to the other Party within [***] after the end of such [***] period; provided that Recipient shall reimburse BMS its cost of Manufacture and supply (including shipping, taxes and duty, if applicable) for any BMS Study Drug supplied to Recipient for the Combined Therapy Clinical Trial prior to such termination.

12.2 Termination for Material Breach.

(a) Notice and Cure Period. If a Party (the "***Breaching Party***") is in material breach of its obligations under this Agreement, the other Party (the "***Non-Breaching Party***") shall have the right to give the Breaching Party notice specifying the nature of such material breach. The Breaching Party shall have a period of [***] after receipt of such notice to cure such material breach (the "***Cure Period***") in a manner reasonably acceptable to the Non-Breaching Party. For the avoidance of doubt, this provision is not intended to restrict in any way either Party's right to notify the other Party of any other breach or to demand the cure of any other breach.

(b) Termination Right. The Non-Breaching Party shall have the right to terminate this Agreement, upon written notice, in the event that the Breaching Party has not cured such material breach within the Cure Period, *provided, however, that* if such breach is capable of cure but cannot be

cured within the Cure Period, and the Breaching Party commences actions to cure such material breach within the Cure Period and thereafter diligently continue such actions, the Breaching Party shall have an additional [***] to cure such breach. If a Party contests such termination pursuant to the dispute resolution procedures under Section 13.3, such termination shall not be effective until a conclusion of the dispute resolution procedures in Section 13.3, as applicable, resulting in a determination that there has been a material breach that was not cured within the Cure Period (which Cure Period shall be tolled for the period from notice of such dispute until resolution of such dispute pursuant to Section 13.3 or abandonment of such dispute by the disputing Party).

12.3 Termination for Bankruptcy. Either Party may terminate this Agreement if, at any time, the other Party shall file in any court or agency pursuant to any statute or regulation of any state, country or jurisdiction, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of such other Party or of such other Party's assets, or if the other Party proposes a written agreement of composition or extension of its debts, or if the other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed or stayed within [***] after the filing thereof, or if the other Party will propose or be a party to any dissolution or liquidation, or if the other Party shall make an assignment for the benefit of its creditors.

12.4 Termination due to Material Safety Issue; Clinical Hold.

(a) Either Party shall have the right to terminate this Agreement immediately (after meeting and discussing with the other Party in good faith as described in the following sentence) upon written notice if it deems it necessary to protect the safety, health or welfare of subjects enrolled in the Combined Therapy Clinical Trial due to the existence of a Material Safety Issue. In the event of a termination due to a Material Safety Issue, prior to the terminating Party providing written notice, each Party's safety committee shall, to the extent practicable, meet and discuss in good faith the safety concerns raised by the terminating Party and consider in good faith the input, questions and advice of the non-terminating Party, but should any dispute arise in such discussion, the dispute resolution processes set forth in Section 13.3 shall not apply to such dispute and the terminating Party shall have the right to issue such notice and such termination shall take effect without the Parties first following the procedures set forth in Section 13.3.

(b) If a Clinical Hold with respect to either the BMS Study Drug or the Recipient Study Drug should arise at any time after the Effective Date, the Parties will meet and discuss the basis for the Clinical Hold, how long the Clinical Hold is expected to last, and how they might address the issue that caused the clinical hold. If, after [***] of discussions following the Clinical Hold, either Party reasonably concludes that the issue adversely impacts the Combined Therapy Clinical Trial and is not solvable or that unacceptable and material additional costs/delays have been and/or will continue to be incurred in the conduct of the Combined Therapy Clinical Trial, then such Party may immediately terminate this Agreement.

12.5 Effect of Termination. Upon expiration or termination of this Agreement, (a) the licenses granted to the Recipient to conduct the Combined Therapy Clinical Trial in Section 3.1 (and any sublicenses granted under Section 3.2) shall terminate, and (b) the Parties shall use reasonable efforts to wind down activities under this Agreement in a reasonable manner and avoid incurring any additional expenditures or non-cancellable obligations; *provided that*, in the case of termination pursuant to Section 12.4, the Recipient may continue to dose subjects enrolled in the Combined Therapy Clinical Trial through completion of the Protocol if dosing is required by the applicable Regulatory Authority(ies) and/or Applicable Law. Any such wind-down activities will include the return to BMS, or destruction, of all BMS Study Drug provided to the Recipient and not consumed in the Combined Therapy Clinical Trial, except in the event that the Recipient terminates this Agreement pursuant to Section 12.2 or 12.3, in which case the Recipient shall continue to have the right to use any BMS Study Drug provided to Recipient for the conduct of the Combined Therapy Clinical Trial.

12.6 Survival. The following Articles and Sections of this Agreement and all definitions relating thereto shall survive any expiration or termination of this Agreement for any reason: Section 2.1(b), Section 2.4, Section 4.5, Sections 5.1(e)-(h), Section 5.1(j), Section 5.1(k), Section 5.1(o), Article 6 ("*Intellectual Property*"), Article 7 ("*Costs and Expenses)*, Article 8 ("*Records and Study Data*"), Article 9

("*Confidentiality*"); Article 10 ("*Representations and Warranties*"), Article 11 ("*Indemnification*"), Section 12.5 ("*Effect of Termination*"), Section 12.6 ("*Survival*"), Section 13.1 ("*Entire Agreement*"), Section 13.2 ("*Governing Law*"), Section 13.3 ("*Dispute Resolution*"), Section 13.4 ("*Injunctive Relief*"), Section 13.6 ("*Notices*"), Section 13.7 ("*No Waiver, Modifications*"), Section 13.8 ("*No Strict Construction*"), Section 13.9 ("*Independent Contractor*"), Section 13.10 ("*Assignment, Licenses*"), Section 13.11 ("*Headings*"), Section 13.13 ("*Severability*"), Section 13.15 ("*No Benefit to Third Parties*"), and Section 13.16 ("*Construction*").

ARTICLE 13

MISCELLANEOUS

13.1 Entire Agreement. The Parties acknowledge that this Agreement shall govern all activities of the Parties with respect to the Combined Therapy Clinical Trial from the Effective Date forward. This Agreement, including the Exhibits hereto and together with the Supply and Quality Documentation, sets forth the complete, final and exclusive agreement between the Parties concerning the subject matter hereof and supersedes all prior agreements and understandings between the Parties with respect to such subject matter. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties with respect to such subject matter other than as are set forth in this Agreement. All Exhibits attached hereto are incorporated herein as part of this Agreement.

13.2 Governing Law. This Agreement shall be governed and construed in accordance with the internal laws of the State of Delaware, USA, excluding any choice of law rules that may direct the application of the laws of another jurisdiction.

13.3 Dispute Resolution.

(a) The Parties' Designated Clinical Contacts (for clinical and regulatory matters) and the Parties Designated Supply Contacts (for supply matters) shall attempt in good faith to resolve any dispute or concern that either Party may bring to the other Party's attention.

(b) In the event of any dispute, controversy or claim arising out of, relating to or in connection with any provision of this Agreement (each a "***Dispute***"), other than a Publication Dispute or a dispute as to whether a Material Safety Issue exists, that cannot be resolved by the applicable Designated Contacts of each Party after a period of [*******], then upon the request of either Party by written notice, the Parties shall refer such Dispute to the Executive Officers. This Agreement shall remain in effect during the pendency of any such dispute. In the event that no resolution is made by the Executive Officers (or their designee) in good faith negotiations within [*******] after such referral to them, then:

(i) if such Dispute constitutes an Arbitration Matter, such Dispute shall be resolved through arbitration in accordance with the remainder of this Section 13.3; *provided, however, that* with respect to any such Arbitration Matter Dispute that relates to a matter described in Section 13.4, either Party shall have the right to seek an injunction or other equitable relief without waiting for the expiration of such [*******] period;

(ii) if such Dispute constitutes a Publication Dispute, the specific dispute resolution processes contained in Section 9.6(b) will apply;

(iii) if such Dispute regards the supply, quality or compliance with specifications of the Recipient Study Drug, the Recipient shall have the final say regarding such Dispute; *provided that* (A) the Recipient shall have no authority to amend, change or waive compliance with this Agreement, which matters may be approved only by the written consent of both Parties, (B) all determinations made by the Recipient shall be consistent with the terms of this Agreement;

(iv) if such Dispute regards the supply, quality or compliance with specifications of the BMS Study Drug, BMS shall have the final say regarding such Dispute; *provided that*

(A) BMS shall have no authority to amend, change or waive compliance with this Agreement, which matters may be approved only by the written consent of both Parties, (B) all determinations made by BMS shall be consistent with the terms of this Agreement.

If a Dispute that constitutes an Arbitration Matter remains unresolved after escalation to the Executive Officers as described above, either Party may refer such matter to arbitration as described herein. Any arbitration of an Arbitration Matter under this Agreement shall be shall be conducted under the auspices of the American Arbitration Association by a panel of three (3) arbitrators pursuant to that organization's Commercial Arbitration Rules then in effect.

(c) The fees and expenses of the arbitrators shall be borne in equal shares by the Parties. Each Party shall bear the fees and expenses of its legal representation in the arbitration. The arbitral tribunal shall not reallocate either the fees and expenses of the arbitrators or of the Parties' legal representation. The arbitration shall be held in New York, New York, which shall be the seat of the arbitration. The language of the arbitration shall be English.

13.4 Injunctive Relief. Notwithstanding anything herein to the contrary, a Party may seek an injunction or other injunctive relief from any court of competent jurisdiction in order to prevent immediate and irreparable injury, loss or damage on a provisional basis. For the avoidance of doubt, if either Party (a) discloses Confidential Information of the other Party other than as permitted under Article 9, (b) uses (in the case of the Recipient) the BMS Study Drug or BMS Technology or (in the case of BMS) the Recipient Study Drug or Recipient Technology in any manner other than as expressly permitted under this Agreement or (c) otherwise is in material breach of this Agreement and such material breach could cause immediate harm to the value of the Recipient Study Drug (by the Recipient) or the BMS Study Drug (by BMS), the other Party shall have the right to seek an injunction or other equitable relief precluding the other Party from continuing its activities related to the Combined Therapy Clinical Trial without waiting for the conclusion of the dispute resolution procedures under Section 13.3.

13.5 Force Majeure. The Parties shall be excused from the performance of their obligations under this Agreement (other than the payment of monies owed to the other Party) to the extent that such performance is prevented by force majeure and the non-performing Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting force majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. For purposes of this Agreement, force majeure shall mean acts of God, strikes or other concerted acts of workers, civil disturbances, fires, earthquakes, acts of terrorism, floods, explosions, riots, war, rebellion, sabotage or failure or default of public utilities or common carriers or similar conditions beyond the control of the Parties.

13.6 Notices. Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement and shall be deemed to have been sufficiently given for all purposes if such notice is timely and is: (a) mailed by first class certified or registered mail, postage prepaid, return receipt requested, (b) sent by express delivery service, or (c) personally delivered. Unless otherwise specified in writing, the mailing addresses of the Parties shall be as described below.

For the Recipient:	Replimune Inc. 18 Commerce Way Wolburn, MA 10801 Attention: Rob Coffin, CEO
For BMS:	Bristol-Myers Squibb Company Route 206 and Province Line Road Princeton, NJ 08543-4000 Attention: VP, Business Development
With a copy to:	Bristol-Myers Squibb Company Route 206 and Province Line Road

Princeton, NJ 08543-4000
Attention: VP & Assistant General Counsel, Licensing and
Business Development

Any such communication shall be deemed to have been received when delivered. It is understood and agreed that this Section 13.6 is not intended to govern the day-to-day business communications necessary between the Parties in performing their duties, in due course, under the terms of this Agreement.

13.7 No Waiver; Modifications. It is agreed that no waiver by a Party hereto of any breach or default of any of the covenants or agreements herein set forth shall be deemed a waiver as to any subsequent and/or similar breach or default. No amendment, modification, release or discharge shall be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties.

13.8 No Strict Construction. This Agreement has been prepared jointly and shall not be strictly construed against either Party. No presumption as to construction of this Agreement shall apply against either Party with respect to any ambiguity in the wording of any provision(s) of this Agreement irrespective of which Party may be deemed to have authored the ambiguous provision(s).

13.9 Independent Contractor. The Parties are independent contractors of each other, and the relationship between the Parties shall not constitute a partnership, joint venture or agency. Neither Party shall be the agent of the other or have any authority to act for, or on behalf of, the other Party in any matter.

13.10 Assignment; Licensees.

(a) Assignment. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other Party, *except* that a Party may make such an assignment without the other Party's consent (i) to an Affiliate, (ii) to a Third Party that merges with, consolidates with or acquires substantially all of the assets or voting control of the assigning Party or (iii) to a Third Party that acquires all the rights of the assigning Party to the Recipient Study Drug, in the case of the Recipient, or the BMS Study Drug, in the case of BMS. If assigned or transferred to an Affiliate, the assigning/transferring Party shall remain jointly and severally responsible and liable with the assignee/transferee Affiliate for the assigned rights and/or obligations. If assigned to a Third Party, any permitted successor or assignee of rights and/or obligations hereunder shall, in a writing to the other Party, expressly assume performance of such rights and/or obligations. Any assignment or attempted assignment by any Party in violation of the terms of this Section 13.10(a) shall be null and void and of no legal effect.

(b) Licensees. If a Party grants a third party a license (other than a license solely to make a product for a Party and other than any license rights granted to Ono for the Ono Territory) to develop and commercialize its Single Agent Compound on a worldwide basis or in any geographic region and/or for all purposes or a limited field, (a "***Licensee***"), such Party will obtain the Licensee's agreement to abide by the terms of this Agreement as and to the extent necessary in order for its obligations hereunder to be fulfilled in the same manner as the licensing Party; and in such event the licensing Party may exercise its rights granted hereunder (including rights to use Study Data and practice Inventions) through the Licensee.

13.11 Headings. The captions to the several Sections and Articles hereof are not a part of this Agreement, but are included merely for convenience of reference only and shall not affect its meaning or interpretation.

13.12 Counterparts. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one (1) and the same instrument. This Agreement may be executed by facsimile or electronic (e.g., pdf) signatures and such signatures shall be deemed to bind each Party hereto as if they were original signature.

13.13 Severability. If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future law, and if the rights or obligations of a Party under this Agreement will not be materially and adversely affected thereby, (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement shall remain in full force and

effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom and (d) in lieu of such illegal, invalid or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the Parties.

13.14 Further Assurance. Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary or as the other Party may reasonably request in order to perfect any license, assignment or other transfer or any properties or rights under, or pursuant, to this Agreement.

13.15 No Benefit to Third Parties. The representations, warranties and agreements set forth in this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and they shall not be construed as conferring any rights on any other parties.

13.16 Construction.

(a) General. Except as otherwise explicitly specified to the contrary, (i) references to a Section, Article or Exhibit means a Section or Article of, or Exhibit to, this Agreement and all subsections thereof, unless another agreement is specified, (ii) references to a particular statute or regulation include all rules and regulations promulgated thereunder and any successor statute, rules or regulations then in effect, in each case including the then-current amendments thereto, (iii) words in the singular or plural form include the plural and singular form, respectively, (iv) the terms “including,” “include(s),” “such as,” and “for example” used in this Agreement mean including the generality of any description preceding such term and will be deemed to be followed by “without limitation”, and (v) the words “hereof,” “herein,” “hereunder,” “hereby” and derivative or similar words refer to this Agreement. No presumption as to construction of this Agreement shall apply against either Party with respect to any ambiguity in the wording of any provision(s) of this Agreement irrespective of which Party may be deemed to have authored the ambiguous provision(s).

(b) No Response. Except as expressly set forth in this Agreement, where a provision of this Agreement provides for a Party to respond within a designated period following written notice from the other Party, and if such Party fails to respond, then the failure to respond shall not be deemed to create or imply: (i) that the non-responding Party agrees or disagrees with the proposed action to be taken by the other Party, (ii) any amendment, change or waiver of the terms of this Agreement, or (iii) any consent that an action proposed to be taken may be taken if it conflicts with the terms of this Agreement and/or waiver of any rights it may have to seek remedies at law or in equity for breach of this Agreement as a result of the action taken

[*Signature page follows*]

IN WITNESS WHEREOF, the Parties, intending to be legally bound hereby, have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

Replimune Inc.		**Bristol-Myers Squibb Company**	
By:	/s/ Robert Coffin	By:	/s/ Fouad Namouni
Name:	Robert Coffin	Name:	Fouad Namouni, MD
Title:	CEO	Title:	Head of Oncology Development
Date:	12th April 2019	Date:	April 11, 2019

APPENDIX A

DRAFT PROTOCOL SUMMARY

[***]

Exhibit 21.1

Subsidiaries of Replimune Group, Inc.

Name of Subsidiary	Jurisdiction
Replimune, Inc.	Delaware
Replimune Limited	United Kingdom
Replimune Securities Corporation	Massachusetts
Replimune (Ireland) Limited	Ireland

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Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-233147) and Form S-8 (No. 333-226323) of Replimune Group, Inc. of our report dated June 3, 2020 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
Boston, Massachusetts
June 3, 2020

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Exhibit 31.1

CERTIFICATION PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Philip Astley-Sparke, certify that:

1. I have reviewed this Annual Report on Form 10-K of Replimune Group, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: June 3, 2020

By: /s/ PHILIP ASTLEY-SPARKE

Philip Astley-Sparke
Chief Executive Officer
(Principal Executive Officer)

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Exhibit 31.2

CERTIFICATION PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jean Franchi, certify that:

1. I have reviewed this Annual Report on Form 10-K of Replimune Group, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: June 3, 2020

By: /s/ JEAN FRANCHI

Jean Franchi
Chief Financial Officer
(Principal Financial Officer)

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Exhibit 32.1

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report on Form 10-K of Replimune Group, Inc. (the "Company") for the fiscal year ended March 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Philip Astley-Sparke, Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: June 3, 2020

By: /s/ PHILIP ASTLEY-SPARKE

Philip Astley-Sparke
Chief Executive Officer
(Principal Executive Officer)

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Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Replimune Group, Inc. (the "Company") for the fiscal year ended March 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Jean Franchi, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: June 3, 2020

By: /s/ JEAN FRANCHI

Jean Franchi
Chief Financial Officer
(Principal Financial Officer)

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